

**PREVALENCE OF PERIPHERAL NEUROPATHY AND ITS  
ELECTROPHYSIOLOGICAL TYPES IN SYSTEMIC LUPUS  
ERYTHEMATOSUS PATIENTS AT KENYATTA NATIONAL  
HOSPITAL**

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## **DEDICATION**

I dedicate this work to my lovely daughter Ella Mabel Atieno.

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## LIST OF ACRONYMS AND ABBREVIATIONS

ACR	American College of Rheumatology
ANA	Anti Nuclear antibodies
AZA	Azathioprine
CRF	Chronic Renal Failure
CV	Conduction Velocity
DM	Diabetes Mellitus
HRQOL	Health Related Quality Of Life
HCQS	Hydroxychloroquine
IQR	Interquartile Range
KNH	Kenyatta National Hospital
LUPUSQOL	Lupus Quality of Life
MMF	Mycophenolate Mofetil
MRC	Medical Research Council
NPSLE	Neuropsychiatric Syndromes of systemic Lupus Erythematosus
PI	Principle Investigator
SF-36	Short Form (36) Health Survey
SLE	Systemic Lupus Erythematosus
SLICC	Systemic Lupus International Collaborating Clinics
UoN	University of Nairobi

## ABSTRACT

**Background:** Peripheral neuropathy which is one of the neuropsychiatric syndromes of SLE, develops in 2% to 36% of patients. Poor quality of life scores and high disease activity indices have been associated with it. Benefits of early identification and treatment on the progression and severity of neuropathy have been demonstrated in studies. There is inadequate data on neurological manifestations of SLE in Africa.

**Objective:** To determine the prevalence of peripheral neuropathy and its electrophysiological types and to determine and correlate quality of life with presence of peripheral neuropathy among patients with SLE attending the rheumatology clinic at Kenyatta National hospital (KNH).

**Methodology:** A Cross-sectional Study was carried out at Kenyatta National Hospital, Rheumatology outpatient clinic. The study consecutively selected Forty eight patients who were 18 years and above with a diagnosis of SLE as per the 2012 Systemic Lupus International Collaborating Clinics (SLICC) criteria. Clinical information and Socio-demographic data were retrieved from the medical records of the patients. Structured history and clinical examination was performed on all patients as per the study proforma. Administration of Lupus quality of life questionnaire was done and all patients had nerve conduction studies performed. Data was analyzed using version 25.0 of SPSS.

**Results:** Peripheral neuropathy prevalence was 60.4 % ( 29 out of 48). Twenty seven point one percent (13) of them had abnormal nerve conduction studies and were symptomatic for peripheral neuropathy while 25 % ( 12) had normal nerve conduction studies despite being symptomatic for peripheral neuropathy. Whereas 8.3 % ( 4) were asymptomatic and had abnormal nerve conduction studies.

Demyelination was the most common nerve conduction pathology at 9(52.94%, n=17). Nevertheless on excluding 5 patients found to have carpal tunnel syndrome, then 4(23.52% n=17) patients had demyelination. Whereas 5(29.41% n=17) patients were found to have axonopathy. Motor neuropathy was the most prevalent nerve conduction syndrome at 52.94% (n=17). The correlation between the presence of peripheral neuropathy with lower quality of life scores involving the domains of physical health ( $p < 0.001$ ), pain ( $p = 0.012$ ), planning ( $p = 0.003$ ), and fatigue ( $p = 0.005$ ) was significant.

**Conclusion:**

Among SLE patients there is a high prevalence of peripheral neuropathy, with variable electrophysiologic and clinical presentation. In affected patients, Quality of life is scores are lower.

## 1.0 CHAPTER ONE

### INTRODUCTION

Systemic Lupus Erythematosus is a disease that is characterized by a variety of clinical presentations that involves almost all tissues and organs, and it results from chronic autoimmune inflammation(1,2). The prevalence rates reported worldwide varies with geographic location, race and ethnicity ranging from 20 to 150 cases per 100,000 (3–6). Due to increased identification of mild disease and improved diagnostic evaluations, the incidence has increased over the years (5).

The actual burden of SLE is unknown in Africa. It was thought to be rare in tropical Africa, however, recent studies and reports show that SLE is common among blacks living in Africa(7–12). In Kenya, the number of patients diagnosed to have systemic lupus erythematosus has been rising over the years (13–16).

Patients with SLE have a relatively high mortality of 14.5% as compared to patients with other rheumatic conditions, and this has mainly been attributed to active disease and organ failure(17–21). In spite of this, it has been observed that SLE patients are now living longer due to early disease recognition and early treatment and therefore likely to experience long term complications (22,23). Long term morbidity in SLE patients has been associated with disability, poor quality of life, high health costs and inability to work, therefore leading to a significant indirect and direct costs to the person and the community(24–29). In Kenya, Odhiambo J et al assessed health related quality of life in patients with SLE and found that these patients have poor quality of life and this correlated with advance in age in the domains of physical health, burden to others, emotional health and fatigue(14).

In the nervous system SLE affects both the central and peripheral system. It is one of the major causes of morbidity and mortality among SLE patients (30).Neurological manifestations of SLE occur in 10% - 90% of patients either before diagnosis of SLE or during the course of disease(31–35). There is paucity of data in Africa on the prevalence of neurological disorders among patients with SLE. A study by Wadee et al from South Africa found a prevalence of 15.9% whereas from Kenya, Genga et al reported a prevalence of 19% (16,36). In these low numbers of neurological disorders, neuropathies were not included and were predominately presented by patients with new onset seizures, psychosis, and stroke. Other studies done in Africa assessing the clinical features of SLE did not report on the neurological manifestations (7,37). The central nervous system manifestations consists of

aseptic meningitis , cerebrovascular accidents, demyelinating disorders , headache, involuntary movements like chorea, myelopathy, acute confusional states, cognitive dysfunction, mood disorder, seizures ,psychosis and cranial nerve palsies as defined by The ACR nomenclature and case definitions for neuropsychiatric syndromes(38). While the peripheral nervous system manifestation are Guillain-barre syndrome , autonomic disorder, mononeuropathy, polyneuropathy and plexopathy(38).

Peripheral neuropathy in SLE develops in 2 % to 36% of patients and may occur due to the disease process itself or due to medications used to treat it. Poor quality of life and high disease activity has been associated with it among patients.

## **2.0 CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.1 Peripheral Neuropathy and Systemic Lupus Erythematosus**

Peripheral neuropathy which is impairment to the peripheral process or cell body of motor autonomic , or sensory nerves develops either in combination or singly(2).

Clinically peripheral neuropathy can be classified according to the distribution of the nerves involved, as proximal or distal and symmetrical or focal asymmetrical. In addition it can be classified depending on temporal evolution as acute occurring within days to 4 weeks , whereas sub acute occurring between 4 weeks to 8 weeks and chronic that occurs for more than 8 weeks (2). It is classified electrophysiologically as myelinopathy affecting the myelin sheath , axonopathy affecting the axon, and ganglionopathy or neuronopathy that affects the cell body (2). Moreover, axonal neuropathy is classified as sensorimotor, mononeuritis multiplex and sensory, while demyelinating neuropathy is classified as acute inflammatory demyelinating polyneuropathy( AIDP) and chronic demyelinating polyneuropathy(2,39).

Peripheral neuropathy is one of the neuropsychiatric syndromes of SLE and it includes acute inflammatory demyelinating radiculopathy ( Guillen –Barre Syndrome) , myasthenia gravis, cranial neuropathy, plexopathy, autonomic disorder, polyneuropathy and mononeuropathy – single / multiplex as defined by the 1999 revised American College of Rheumatology (38). Studies done recently have reported Plexopathy and Guillen-Barre syndrome in SLE to be rare (32,40). However, Small fiber neuropathy has been found to be common in SLE patients, and it has not been described in 1999 ACR case definitions of neuropsychiatric syndromes (40,41). Oomatia et al described that 17.1% of patients who had peripheral neuropathy in SLE were found to have small fiber neuropathy while acute inflammatory demyelinating radiculopathy and plexopathy described in the criteria were noted to be scarce (40). Similarly, Lasse G et al found that 13% of patients with peripheral neuropathy in SLE had features consistent with small diameter nerve neuropathy (41).

#### **2.2 Pathogenesis of Peripheral Neuropathy In SLE**

It is postulated that chronic inflammation or immune mediated injury to the vasa nervorum results in vasculitic injury therefore causing peripheral neuropathy in SLE. This is mainly as a result of vascular wall immune complexes deposition (42). Eventually , this leads to the progressive dysfunction of nerves over time as burden of lesion increases(43).

Due to small local injury to peripheral nerve, transient focal conduction block then occurs whereas intermediate injury that necessitates a prolonged time of recovery leads to focal demyelination. In Severe nerve insult, wallerian degeneration takes place in the distal segment of the axons hence regeneration of axons from the proximal segment(44) .

Demyelination of the peripheral nerves in SLE may lead to chronic sensorimotor and sensory polyneuropathy, though the pathophysiology of this entity is not fully understood. Acutely it may exhibit pathophysiology resembling acute inflammatory demyelinating polyradiculopathy and may mimic Guillan-Barre syndrome (43).Myopathy may occur as a result of inflammatory cascades. Steroid therapy in SLE can also lead to myopathy presenting as atrophy of muscle fibers without inflammatory infiltrates.(43). Neuromuscular Junction involvement in SLE may clinically resemble Myasthenia Gravis (43).

Anti- malarial medications such as chloroquine , used in the management of rheumatic diseases have been documented to cause mild sensorimotor neuropathy as well as severe vacuolar myopathy with histological studies showing both damage to Schwann cells and axonal degeneration (45). Hydroxychloroquine has been implicated in the causation of neuro-myotoxicity leading to proximal myopathy with myeloid bodies and curvilinear bodies on biopsies, with duration and dosage of drug not being well defined in myopathy(46).

An immunomodulating drug , Leflunamide, used in the treatment of SLE has also been shown to cause motor axonal neuropathy that reversed after 3 months of stopping treatment (47).

### **2.3 Clinical Features and Risk Factors Associated with Peripheral Neuropathy in SLE**

Peripheral neuropathy in SLE presents with symptoms and signs similar to the other causes of neuropathy. The Clinical presentation depends on the types of peripheral nervous system involved. The motor involvement may present as either asymmetrical or symmetrical weakness involving the distal or proximal extremity or even both of these(2).On the other hand sensory presentations include numbness, hyperpathia, allodynia, tingling , burning or arching sensations(2). Autonomic symptoms are mainly heat intolerance, dysfunction of bowel and bladder , fainting spells, and orthostatic light headness (2).

Yu-Jih-Su et al found that 11 out of 15 patients (73.3%) had at least one clinical symptom of peripheral neuropathy. Numbness and functional gastrointestinal problems were the most prevalent symptoms associated with neuropathy in SLE each occurring in 8 out of 15 patients (53.3%), in patients with lupus nephritis (48) .



Renu Saigal et al found that 9 out of the 50(18%) patients studied had clinical neuropathy. Eight (88.9%) out of the 9 patients had more of the sensory symptoms which included varied intensity of diminished perception to vibration, touch, pain, and temperature in distal parts. These patients also had varied degree of motor weakness in their distal muscles of upper and lower limb. The remaining 1(11.1%) out of 9 patients had diminished deep tendon reflexes in the lower limbs (49).Khean Jin et al on the other hand reviewed 50 consecutive in – patients with SLE in 1996 and found that 14 patients (28%) had objective signs of peripheral neuropathy. 7 of the patients out of the 14 (50%) with clinical neuropathy had reduced deep tendon reflexes in the lower limbs , 3 patients(21.4%) had intrinsic muscle wasting and 1patient had left sciatic nerve involvement(50).

Tavares et al reported 5 out 5 patients (100%) to have muscular weakness and 3 out of 5 patients (60%) to have hyporeflexia in juvenile systemic lupus erythematosus patients. Two out of 5 patients (40%) were reported to have presented with hyperesthesia and 1 out of 5(20%) had paresthesia in the same cohort of juvenile SLE patients (51). Wang xiabian et al found that 50.6% of the SLE patients with Peripheral neuropathy presented with Muscle weakness and numbness. 38.4% of the patients had pain on the affected regions and 63.7% of patients had symmetrical involvement. They also reported that younger female patients with myasthenia gravis had increased risk of developing SLE and a predilection of developing neuropathy (52).

Simone Fargeti et al in a retrospective study done in Brazil found that the interval between the diagnosis of peripheral neuropathy and onset of SLE was as short as  $4.9 \pm 5.7$  years (53).

Certain factors have been associated with the development of peripheral neuropathy in SLE such as auto antibodies and complement immunoglobulins. Wang Xiabian et al in a study in China found that patients with immunoglobulin G had a higher frequency of getting peripheral neuropathy as compared with those without it (52). Yu-Jih-Su in a retrospective study in China also found that presence of anti –Rho was significantly associated with neuropathy related to SLE(48). Simone Fargeti et, al also were able to correlate the presence of anti-sm antibodies, hematological involvement , leucopenia , lymphopenia and cutaneous vasculitis with the development of peripheral neuropathy in SLE (53). Tavares et al noted presence of antiphospholipid antibodies in patient with peripheral neuropathy and juvenile systemic lupus erythematosus(51).

Studies have shown that peripheral neuropathy among patients with SLE is associated with a high disease activity index as found by Brundusa Florica et al and Simone Fargeti et al (53,54).

## **2.4 Impact of Peripheral Neuropathy on Quality Of Life in SLE Patients**

Brundusa florica et al looked at health related quality of life assessing the mental and physical component summary of SF-36 question and they found that compared with patients without peripheral neuropathy , those with peripheral neuropathy had a substantially lower SF- 36 score. This was mainly associated with the tendency for asymmetric and lower extremity involvement especially peroneal and sural nerve(54) .

R. Jasmin et al in their study of clinical and electrophysiological characteristics of symmetric polyneuropathy in a cohort of SLE patients assessed the function and health related quality of life using the modified Rankin scale and SF-36 score. They found that there was no difference in the quality of life scores in these cohorts of patients(55).

## **2.5 Diagnosis of Peripheral Neuropathy in SLE**

The various diagnostic modalities of peripheral neuropathy involve the use of both clinical and electrophysiological studies.

### **2.5.1 Clinical Diagnosis**

Clinical diagnostic criteria have been used widely to assess for peripheral neuropathy especially in circumstance where electrophysiological studies are not available. The limitation of using the clinical diagnostic criteria is in the possibility of not being able to capture those patients with subclinical neuropathy.

Clinical diagnosis involves screening for neuropathic symptoms and sign.

The clinical tools that have been used to assess peripheral neuropathy in Kenya have mainly been used in patients with HIV. The tools used have mainly been the brief peripheral neuropathy screen which was found to have a low sensitivity and specificity as compared to other tools in study carried out by Deanna cettomai et al. in their study that was evaluating the utility of quantitative sensory testing and screening tools in identifying HIV associated peripheral neuropathy in western Kenya(56).

Quantitative sensory testing which uses physical vibratory and thermal stimulation devices to deliver electrical impulses at specific frequency have been recommended by AAN for clinical and research studies though this should not be used as a sole criteria for identification for sensory neuropathy(57).

### **2.5.2 Electrodiagnostic Testing**

The use of nerve conduction studies is dated back to the 19<sup>th</sup> century when Galvani first performed it on frogs and observed twitching of muscles and electrical stimulation, later on François Magendie was able to differentiate anterior and posterior spinal root stimulations on dogs(58). The use of needle and percutaneous techniques were eventually performed by Sarlandice, Guillaiane B Duhane and Carlos Matteuci (58). In 1852 nerve conduction velocity was measured in humans by Herman Von Helmholtz (58). In 1940s Weddel, Hodes, Dawson and Scott were able to publish the use of Nerve conduction studies and electromyogram leading to their usage(58). Over the years there has been better understanding and usage of this test in the evaluation of weakness, muscle wasting and sensory symptoms(58).

Nerve conduction test and needle electromyography are the two major tests carried out in the electro-diagnostic studies which provides additional information on distribution of neuropathy. These diagnostic evaluations give important information on whether the neuropathy is, motor, autonomic and sensory or a combination of both. It further helps to distinguish axonopathy from demyelination and also axonal degeneration secondary to ganglionopathies from the more common length dependent axonopathies(2).

Nerve conduction studies give us information on the location of lesions in the length of nerves and pathophysiological information in terms of axonal or myelin involvement(59). Axonal neuropathy is suggested by low amplitude potentials with relatively preserved conduction velocities, distal latencies and late potentials along with fibrillations on needle electromyography. Whereas primary demyelinating neuropathy have prolonged distal latencies, slow conduction velocities, and late potentials, with relatively preserved amplitude and absence of fibrillations on needle electromyography. On the other hand autonomic studies are used to evaluate small myelinated or unmyelinated nerve fiber involvement such as blood pressure, heart rate response to both Valsalva maneuver, tilt table testing and quantification sudomotor axon reflex testing, all of which are useful in patients who have

pure small fiber neuropathy or autonomic neuropathy in which routine nerve conduction studies are normal (2).

## **2.6 Prevalence and Patterns of Peripheral Neuropathy**

Systemic Lupus Erythematosus being a heterogeneous disease may vary in its prevalence of peripheral neuropathy based on different genetic backgrounds, race and ethnic components. Development of peripheral neuropathy in systemic lupus erythematosus patients is thought to be 2% to 36%, the large discrepancy mainly depends on the criteria used to define peripheral neuropathy(2,49). The prevalence of peripheral neuropathy was inferred to be a rare finding in SLE because many studies in the past defined peripheral neuropathy clinically. Most of these studies used the case definitions of peripheral neuropathy as defined by the 1999 ACR neuropsychiatric syndromes hence missing out on small fiber neuropathy currently thought to occur commonly in SLE patients. Studies that defined peripheral neuropathy electrophysiologically found higher prevalence, mainly because they were able to capture patients who had subclinical neuropathy. Racial differences in these studies may account for the large discrepancy in the prevalence of peripheral neuropathy in SLE patients

In a retrospective study by Wang xiabian et.al on peripheral neuropathy due to SLE in china, found that the prevalence of SLE associated neuropathy was 1.5% which is a figure less than the known figure of 2%. (52). The most common type of neuropathy reported was polyneuropathy at 59.5%, this was followed by mononeuropathy at 13.9%. Plexopathy was however found to be very rare and no case was reported during the study (52). In a retrospective study by Yu – Jih – Su et al carried out a study in Taiwan assessing the association between auto antibodies and peripheral neuropathy in SLE and Lupus nephritis, they were able to demonstrate that the prevalence rate of peripheral neuropathy was 2.68% of which about 73.33% was mixed sensorimotor polyneuropathy, while 13.3% had sensory polyneuropathy (48).

Simone fargeti et al in his retrospective study carried out in Brazil Sao Paulo university also found that the prevalence of peripheral neuropathy in SLE was 2.1%(53) .In this study the most common neuropathy was Sensorimotor polyneuropathy of the lower limbs which was reported at 50%, followed by mononeuropathy at 26.9% and polyradiculopathy at 15.3% (53). Tavares et al also carried out a study on patients with juvenile systemic lupus erythematosus in University of de Sao Paulo Brazil pediatric clinic and reported a prevalence of 2.2%(51).

Oomatia et al reviewed 2097 SLE patients over a period of 25 years and found that 125 patients (5.9%) had peripheral neuropathy(40). Axonal neuropathy was reported to be the most common at 56.1% and most of these patients presented with sensorimotor Axonal Neuropathy at 25.6%, followed by Sensory axonal neuropathy at 23.2% and mononeuritis multiplex at 17.7%. Small fiber neuropathy not defined in the 1999ACR neuropsychiatric syndromes was found to occur commonly in SLE patients at 17.1%.Demyelinating neuropathy was less prevalent at 2.4% and plexopathy was found to be rare occurring in 1.2% of the patients (40).

Brundusa Florica et.al carried out a retrospective study at the University of Toronto clinic on Peripheral neuropathy in patients with SLE and reported a prevalence of 13.5%. The case definition in this population was still defined by the 1999 revised American college of rheumatology neuropsychiatric syndromes(54).The most frequently occurring type of peripheral neuropathy was polyneuropathy at 55.5% of which sensory accounted for 36.7% and sensorimotor at 18.8%. Mononeuropathy was reported to occur at 11.1% and mononeuropathy multiplex 5.3%.Axonal neuropathy was reported to be the most common pattern at 74% in keeping with a vasculitic pathology. While demyelinating neuropathy was reported to develop in 24 % of patients (56).

However some studies that used both clinical and electrophysiological evaluation of both symptomatic and asymptomatic patients with SLE have been able to find that peripheral neuropathy is a common finding and that SLE patients also do present with subclinical neuropathy.

Khean Jin et al in an observational study in 1996 evaluated 50 in-patients with confirmed diagnosis of SLE for peripheral neuropathy using nerve conduction studies and electromyogram. They reported a higher prevalence at 56% of patients with abnormal electrophysiological findings and 28% of patients had abnormal clinical findings of peripheral neuropathy. Hence noting that subclinical neuropathy that is mostly ignored is a common finding in SLE. (50).They reported polyneuropathy to be the most frequent type occurring at 42% of the patient. This was followed by mononeuropathy at 14% and mononeuritis multiplex at 14%. The most common abnormal nerve conduction parameters were prolonged or absent Soleal H reflexes at 28.9% , followed by reduced action potential amplitudes with Compound Muscle action Potential reduced in 14% of the patients and Sensory Nerve action Potential reduced in 9.7% of the patients in keeping with axonal type of neuropathy(50).

Huynh C et al in 1999 carried out a prospective case-control study evaluating 54 patients with SLE and 30 controls using electro-diagnostic criteria found that 15 patients (27.8%) had Peripheral neuropathy as defined by abnormal nerve conduction studies while only 4 patients (7.4%) were symptomatic (60).

In a recent hospital-based observational study carried out between October 2011 and September 2012 by Renu Saigal et al at a tertiary center in north India, evaluating 50 patients with SLE using clinical, neurological examination and nerve conduction studies, found that there was a prevalence of 36% (18 patients ) who had peripheral neuropathy as defined by electrophysiological findings. Of these patients, 18% had clinically evident neuropathy while the other 18% had subclinical neuropathy. They found that axonopathy was the most frequent type of neuropathy occurring in 94.4% of the patients suggesting a vasculitic component. The most common abnormal nerve conduction parameters were reduced Compound Muscle action potential occurring in 13.75% of the patients and reduced Sensory action potential occurring in 6.33% of the patients .Whereas Mononeuritis multiplex occurred in 72.2 % of the patients, 16.67% had mononeuropathy and polyneuropathy developed in 11.1%. Nine (9) of the patients were found to have sensorimotor neuropathy while the other 9 had motor neuropathy. Pure motor peripheral neuropathy was found to be predominantly in subclinical neuropathy. The most common nerves affected in this study were the peroneal nerve followed by the tibial and the sural nerves. The median and the ulnar nerves were less involved therefore suggesting a predominant lower extremity involvement confirming length dependent lower extremity axonopathy(49).

There is inadequate data on prevalence and clinical associations of peripheral neuropathy with SLE in Africa. However, in Cote d' Voire Marium Gbane et al were able to report a case of severe axonal peripheral polyneuropathy revealing SLE , in a 48 year old patient who presented with polyarthrititis and 4 days later following hospitalization developed distal and proximal tetra paresis with an electromyogram carried out showing severe axonal sensory motor polyneuropathy (61). In Tunisia, Ben Salem et al conducted a retrospective study over a period of 14 years and found that 5 patients out of 246(2%) had peripheral neuropathy(62). In Kenya, Genga et al reported a case of a twenty year old patient, newly diagnosed to have systemic lupus erythematosus who presented with acute inflammatory demyelinating polyneuropathy, with electrophysiological survey revealing asymmetrical mixed sensorimotor demyelination and radiculopathy(63).

The table1 below shows studies done on prevalence of Peripheral Neuropathy in SLE.

**Table 1 : A summary of studies done on Prevalance of peripheral neuropathy in SLE patients in different regions**

STUDY	COUNTRY	YEAR	SAMPLE SIZE ( Patients)	PREVALENCE	STUDY DESIGN
BrundusaFlorica et al	Canada – University of Toronto	Jan 1970 – May 2010	1533	13.5%	Retrospective Case control
Oomatia A et al	USA – John Hopkins	25 year study Published 2013	2,097	5.9%	Retrospective Case control
Wang Xiabin et al	China	Jan1995 – Sept 2013	4,924	1.5%	Retrospective Case control
Khean Jin GOH et al	Malaysia-South East Asia	1996	50	56%	Observational Study
Huynh C	Hong Kong	1999	54	27.8%	Prospective case control
RenuSaigal et al	North India	October 2011- Sept 2012	50	36%	Observational Study

## 2.7 Management of peripheral neuropathy in SLE

SLE induced peripheral neuropathy tends to respond to treatment unlike the other causes of peripheral neuropathies. Immunosuppressive treatment is useful in SLE patients with vasculitic neuropathy and its inadequate in treating patients with generalized sensory or sensorimotor polyneuropathy with no evidence of vasculitis(2).

## **2.8 Lupus Quality Of Life Questionnaire (LUPUS QOL)**

This questionnaire is mainly used to determine Health Related Quality of Life in adult patients with SLE. It was developed and validated by MC Elhone et al in 2007(64) in the UK.

Its validity has been assessed and found to be good when compared with other comparable domains of SF-36 (64). Validity was measured by comparing scores in the domain of the LupusQoL with SF-36 and was reported to have a relatively good correlation ( $r$  0.71-0.79) when compared with other comparable domains of (SF-36). Studies done in the US, Spain, and UK found that the LupusQoL has discriminant validity in that it functions relatively independently as an outcome measure in SLE(64).



### **3.0 CHAPTER THREE:**

#### **3.1 JUSTIFICATION**

Peripheral neuropathy one of the manifestations and complications of SLE is known to cause morbidity and disability. Poor quality of life scores and high disease activity indices in SLE patients has been associated with it.

Most of the electrophysiological studies done have shown that an increased percentage of patients with SLE have peripheral neuropathy. Asymptomatic patients with subclinical peripheral neuropathy that are missed on clinical evaluation are diagnosed during nerve conduction studies. If discovered early enough these patients may benefit from early treatment which may reduce disease progression.

There is paucity of data on prevalence of peripheral neuropathy and its various electrophysiological types in SLE patients locally, in Kenya and in Africa as well.

This study was done to increasing clinician awareness of the presence of both symptomatic and asymptomatic peripheral neuropathy, and its types in SLE patients. This study also adds to the scientific knowledge that seeks to determine whether SLE patients should be routinely screened for peripheral neuropathy, and it forms a baseline survey for future studies.

### **3.2 Research Question**

What is the burden of peripheral neuropathy, its electrophysiological types and its associations with quality of life among SLE patients attending the Rheumatology clinic at the Kenyatta National Hospital?

### **3.3 Objectives**

#### **3.3.1 Broad Objectives**

The aim of this study was to determine the prevalence of peripheral neuropathy, its electrophysiological types and its associations with quality of life in SLE patients attending the rheumatology clinic at Kenyatta National Hospital.

#### **Primary Objectives**

- To determine the prevalence of peripheral neuropathy by clinical evaluation and nerve conduction studies in SLE patients attending the rheumatology clinic at Kenyatta National Hospital.
- To describe the electrophysiological types of peripheral neuropathies using nerve conduction studies in SLE patients attending the rheumatology clinic at Kenyatta National Hospital.

#### **Secondary Objectives**

- To determine the quality of life in SLE patients using the Lupus QOL questionnaire
- To correlate quality of life with the presence of peripheral neuropathy in SLE patients.
- To describe the socio-demographic characteristics of SLE patients.

## **4.0 CHAPTER FOUR:**

### **METHODOLOGY**

#### **4.1 Study Design and setting**

This was a hospital based cross-sectional study.

#### **4.2 Study setting**

The study was conducted in the rheumatology out-patient clinic at the Kenyatta National Hospital, which is situated in Nairobi, Kenya.

#### **4.3 Study Population**

The study population comprised of SLE patients diagnosed as per the 2012 SLICC classification criteria for SLE (Appendix1). Patients were included if they were aged eighteen years and above and had provided an informed written consent. Patients were excluded if they were Amputees, had history of traumatic involvement affecting the nerves, had foot ulcerations, as well as those known to have other known causes of peripheral neuropathy such as mixed connective tissues disease, diabetes mellitus, history of heavy alcohol consumption, chronic renal failure and pernicious anemia.

#### **4.4 Sample size calculation and Sampling procedure**

##### **Sample Size calculation**

Sample size was estimated using Fisher et al 1998 formula for prevalence studies then corrected for finite population. The following formula was used:

$$\underline{n = \frac{z^2 (p (1-p))}{e^2}}$$

n – Sample size

z – 1.96 (95% confidence interval)

p – Estimated prevalence of peripheral neuropathy in SLE= 36% from Saigal et al, North India (49)

e – Margin of error (precision error) = ±5 %.

Substituting into the formula, n = 354.

However the total number of SLE patients on follow up at KNH rheumatology clinic between Jan – Dec 2015 was 55. The sample size therefore exceeded the total population. If the target population is less than 10,000 then the final estimate was calculated using the formula:

$$nf = \frac{n}{1 + n/N}$$

Where nf = desired sample size where population < 10,000 , N = total study population ,  
Substituting into the formulae;

$$nf = \frac{354}{1 + 354/55}$$

nf= 47.6. A minimum of 48 patients was required to estimate prevalence of peripheral neuropathy in SLE within a 5 % margin of error.

### **Sampling procedure**

Consecutive sampling was used to recruit the participants. Every SLE patient at the rheumatology clinic meeting the inclusion criteria was recruited until the desired minimum sample size of forty eight patients was attained.

## **4.5 Clinical Procedures**

### **Participant Recruitment and Consenting Procedure**

Files of patients who were eligible for the study were selected and a detailed explanation pertaining to the nature and purpose of the study was given to the participants. Only willing participants who signed a written consent form (See Appendix VI) were recruited.

### **Data Collection Procedure**

The patients' files were reviewed to confirm the diagnosis of SLE and to obtain information on age and disease duration since diagnosis. The eligible participants were interviewed by the PI or a research assistant to obtain a brief clinical history as per the study proforma. (Appendix III). A general examination which focused on the presence or absence of dry skin, loss of hair, skin ulcerations, scars and edema was performed.

A targeted neurological examination which included a sensory and motor examination and nerve conduction studies were conducted as follows:-

#### Sensory examination

- Fine touch was elicited using a soft cotton wool.
- Pain was tested by pricking on the surface of the skin using a shard of a wooden barbeque stick.
- Vibration perception was tested using tuning fork – 128Hz over bony prominences.
- Skin temperature perception was tested using a glass of warm (35 -40°C) and cold water (6-10°C).
- Proprioception was tested by examining joint movements of the big toe and the middle finger with the eyes closed and asking the patient which direction the digit had been moved.

#### Motor examination

- Muscles were inspected and palpated for evidence of wasting
- Tone was tested in the standard way and described as hypotonia, normal tone and hypertonia.
- Power was tested in the standard way and graded 0 -5 according to MRC classification at the ankle, knee, shoulder, elbow and wrist joints and the hand grip.
- Reflexes – deep tendon and superficial reflexes were tested and graded as absent (0), present but reduced (+) as a normal ankle jerk), normal (++) as a normal knee jerk), brisk (+++) and clonus.

This information obtained was recorded in the proforma (AppendixIII) for later analysis.

#### Nerve Conduction Studies

All the nerve conduction studies were performed at room temperature on a Nihon Cohden machine. The tests were each done by a qualified neurologist with experience in electrophysiological studies, and the Principal Investigator assisted with each test after undergoing 2 weeks training. The tests were done at the Neurology Center, an outpatient neurology clinic, which is situated in General Accident House on Ralph Bunche road, Nairobi, Kenya. For each patient one upper limb and one lower limb was tested based on symptom severity, with extra limbs added if clinically indicated.

For asymptomatic patients the selection of the limbs to assess was based on convenience of access. For every patient at least five nerves were tested: the median, the ulnar, the peroneal, the sural and the tibial nerves.

For each nerve the following was done:-

- Amplitude
- Dispersion
- Distal latency/Peak onset latency
- Conduction Velocity
- F- Wave response.

Nerve conduction studies were done using the standard procedure outlined in Appendix VI.

#### LUPUS QUALITY OF LIFE (LUPUSQOL)

The Lupus quality of life questionnaire containing 8 domains was then administered to the patients (Appendix IV).

The 8 domains in the questionnaire included Physical health( 8 items), Emotional health (6 items), Body Image(5 items), Pain ( 3items), Planning(3 items) , fatigue(4 items), Intimate relationships( 2 items ) and Burdens to others (3 items).The questions had a 5 –point likert scale response format (0 all the time, 1 most of the time, 2 a good bit of the time, 3 occasionally, and 4 never).

The mean raw domain score was calculated by totaling the item response scores of the answered items and dividing by the number of answered items. The mean raw domain score was divided by 4 and then multiplied by 100, resulting into scores between 0 and 100, representing the transformed score for that domain. The scores were interpreted as 0 (worst HRQOL) to 100 (best HRQOL).

A non applicable response was treated as unanswered, and only when at least 50% of the items were answered then transformed domain scores were obtained.

## 4.6 Study Variables

### 4.6.1 Independent variables

- Age – was recorded as number of years as documented or reported date of birth.
- Sex – categorized as Male or female
- Marital status – recorded as single , married, divorced or separated
- Treatment Modality- This was defined as drug used, dosage and duration of use. Drugs were classified as steroids, NSAIDS, immunosuppressive agents such as hydroxychloroquine and leflunamide, biological agents.
- Duration of SLE diagnosis –Was defined in months or years from the date of confirmed diagnosis

### 4.6.2 Outcome of Interest

#### Definition of outcome Variable

- I. **Peripheral neuropathy:** was defined as: presence of a symptom, and/or a sign, with or without impairment in nerve conduction studies or such impairment without a sign or symptom.
  - The symptoms diagnostic of neuropathy included any one of (2); Paraesthesiae, Numbness, Tingling sensation, Pins and needles sensation, Hyperpathia, Loss of specific sensory modality e.g. pain, temperature or touch in the peripheral distribution and Neuralgia.
  - The signs diagnostic of peripheral neuropathy included any one of (2); Impaired sensation to touch, pain, vibration, temperature and proprioception in the peripheral distribution, Decreased muscle tone, Loss of power not attributable to muscle disease or spinal cord lesion, Absence of deep tendon reflexes, and Muscle wasting.
- II. **Nerve conduction abnormalities:**
  - Nerve conduction impairment was defined in the following parameters:
    - Nerve Conduction Velocity
    - Amplitude
    - Distal Latency /Peak Onset Latency
    - F-Wave response

The various measures were compared to the accepted ranges for ages(65).

These impairments were further classified as nerve conduction pathologies and nerve conduction syndromes as follows:

**a. Nerve Conduction Pathologies:**

- Axonopathy was defined as : a reduction in the amplitude of the action potentials of various nerves with preservation of the nerve conduction velocities(2). The amplitudes that were used as references in this study were the ones that the machine normally uses from the manufacturer (software stated in the methods). The measures vary according to the nerve in question (see appendix V). Values below this reference range were considered suggestive of axonopathy.
- Demyelination was defined as : a reduction in conduction velocity in the tested nerve to below the reference range for the machine used with prolongation in distal latencies below what was be considered normal for the particular machine to be used (see appendix V)

**b. Nerve conduction syndromes:**

- Sensory neuropathy was considered: if only nerves or components of nerves sub serving sensory modalities were affected.
- Motor neuropathy was considered: if motor nerves or their component were affected.
- Sensori motor was considered: if both the sensory and motor components were affected.
- Mononeuritis multiplex was considered: if simultaneous or sequential involvement of individual noncontiguous nerve trunks, either partially or completely were involved.
- Mononeuropathy was considered: if only one nerve is involved and symptoms and signs were in its distribution.

#### **4.7 Quality Assurance**

The study was carried out with the help of one research assistant who was trained on the administration of the questionnaire and data handling. The Principle Investigator performed a targeted physical examination which was verified by a study dedicated neurophysician. The nerve conduction studies was carried out by a qualified study dedicated neurophysician using standard operating procedures. In cases of discrepancies, two neurophysicians reviewed the nerve conduction studies together and came to a consensus.



#### **4.8 Data Management and analysis**

Data was entered weekly into a password protected Microsoft access data 2013 base. Once data entry was complete, it was cleaned, coded and analyzed using SPSS version 25. Descriptive data of study population such as age, gender, marital status and level of education was summarized in percentages for the categorical data. Continuous data such as duration of SLE disease and medication was summarized using, measures of central tendency (mean or median).

Prevalence of peripheral neuropathy was analyzed and presented as proportions with 95% confidence interval. The types of Peripheral neuropathy were categorized as axonopathy, demyelination, sensory, motor, mononeuropathy, mononeuritis multiplex and presented as proportions. Chi-square tests were used to check for association between patient profile (Sociodemographic characteristic and clinical characteristics) with the presence of Peripheral neuropathy. Chi-square test statistic and corresponding p-values were reported.

Lupus quality of Life was scored and analyzed using a standard scoring system resulting in scores between 0 to 100. The mean of the transformed score with standard deviation was calculated to determine the Health related quality of life in the study population in each domain. Health related quality of life was correlated with Peripheral neuropathy using chi-square analysis.

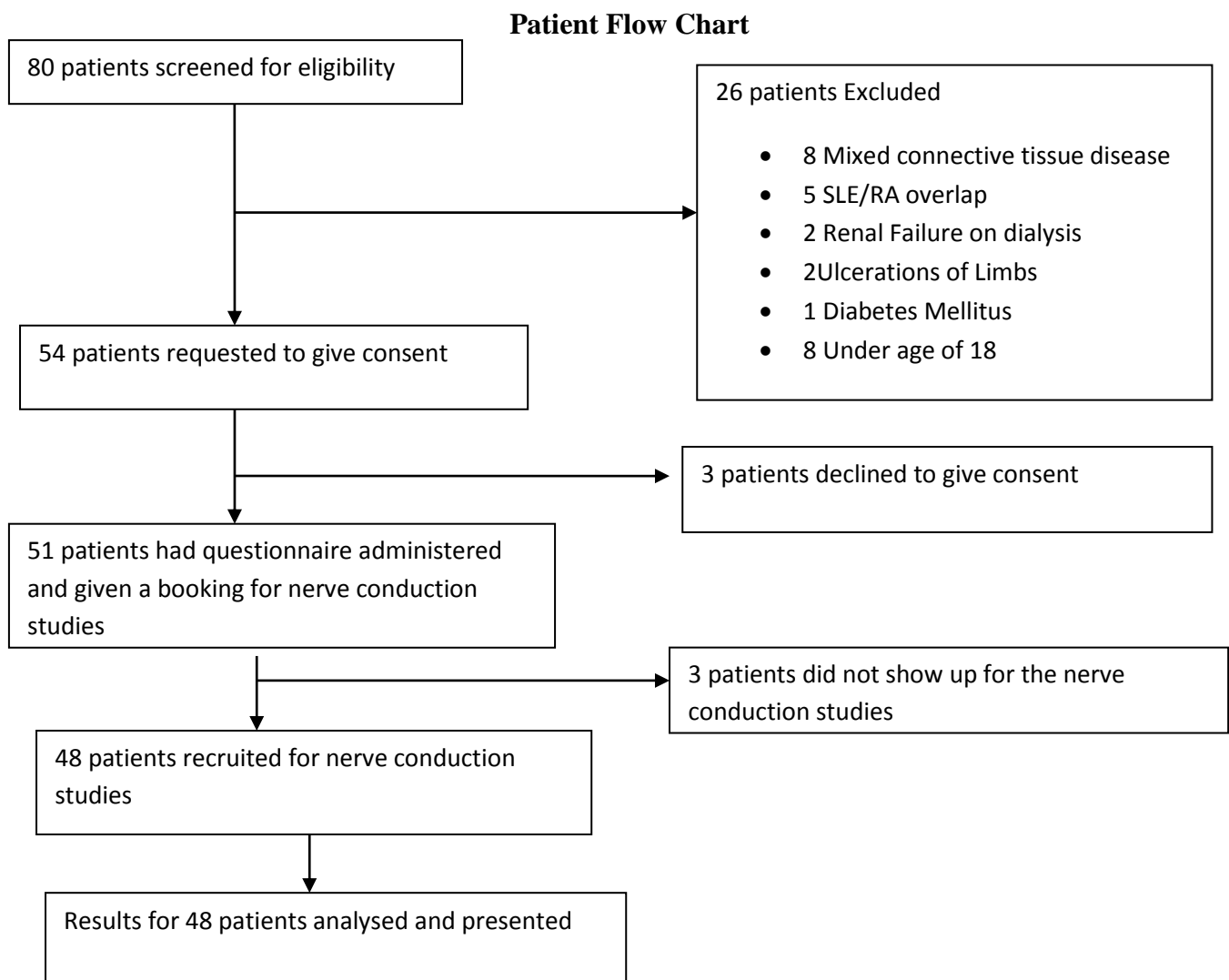
#### **4.9: Ethical Considerations**

The study was carried out after an approval by the department of internal medicine and therapeutics of the University of Nairobi and the KNH – UON ethics review committee. Only patients who gave an informed written consent were recruited. Patient participation in the study was voluntary, and medical attention was not denied for those who declined to participate. Patient confidentiality was strictly maintained at all time. The nerve conduction results were communicated to the patients and a copy of results attached to the patients file. Patients with abnormalities in the nerve conduction studies were referred appropriately. Costs regarding the investigation was borne by the principle investigator.

## 5.0 CHAPTER FIVE

### RESULTS

In a period of three months, between May 2018 and July 2018, 80 patients being managed for SLE were screened for study eligibility. 32 patients were excluded from the study of which 8 had mixed connective tissue disorder , 5 had SLE and Rheumatoid arthritis overlap, 2 had Renal failure, 8 were under the age of 18, 2 had Ulcerations of the limbs, 1 had Diabetes Mellitus, 3 refused to give consent,3 did not show up for Nerve Conduction Studies. Therefore a total of 48 patients were finally recruited for the study and underwent a targeted history and physical examination as per the questionnaire and were booked for Nerve conduction studies either the same day or another day in the course of the week. A summary of the screening procedure is seen in Figure 1.



**Figure 1: Patient flow chart**

## **5.1 Baseline Characteristics Of Study Population**

The study population entirely consisted of females with a mean age of 37.9 years (SD 11.92, SEM 1.72). Majority of the patients at (52.1%), were in the reproductive age group between 20 and 39 years. Approximately 70.8% had some form of employment and at least half (58.3%) were married.

While some of the patients had only been recently diagnosed (1 week prior to the study), others had lived with SLE for as long as 13 years. The Median (IQR) duration of disease since diagnosis was 27.5 (12-60) months. A summary of sociodemographic variables tested for the study is shown in Table 2.

**Table 2: Socio-demographic characteristics of the study population**

<b>Variable</b>	<b>Category</b>	<b>Frequency</b> N=48	<b>Proportion (%)</b>
<b>Gender</b>	Female	48	100%
<b>Age</b>	<20	2	4.2%
	20-39	25	52.1%
	40-59	20	41.6%
	>60	1	2.1%
<b>Marital status</b>	Married	28	58.3%
	Single	16	33.3%
	Separated	3	6.3%
	Divorced	1	2.1%
<b>Residence</b>	Nairobi	23	47.9
	Others	25	52.1
<b>Occupation</b>	Employed	34	70.8%
	Unemployed	14	29.2%
<b>Body mass Index</b>	Underweight	2	4.35%
	Normal	30	63.04%
	Overweight	13	26.09%
	Obese	3	6.52%
<b>Duration since diagnosis in months</b>	The Median(IQR)	27.5 (12-60)	

### Medications taken by study participants

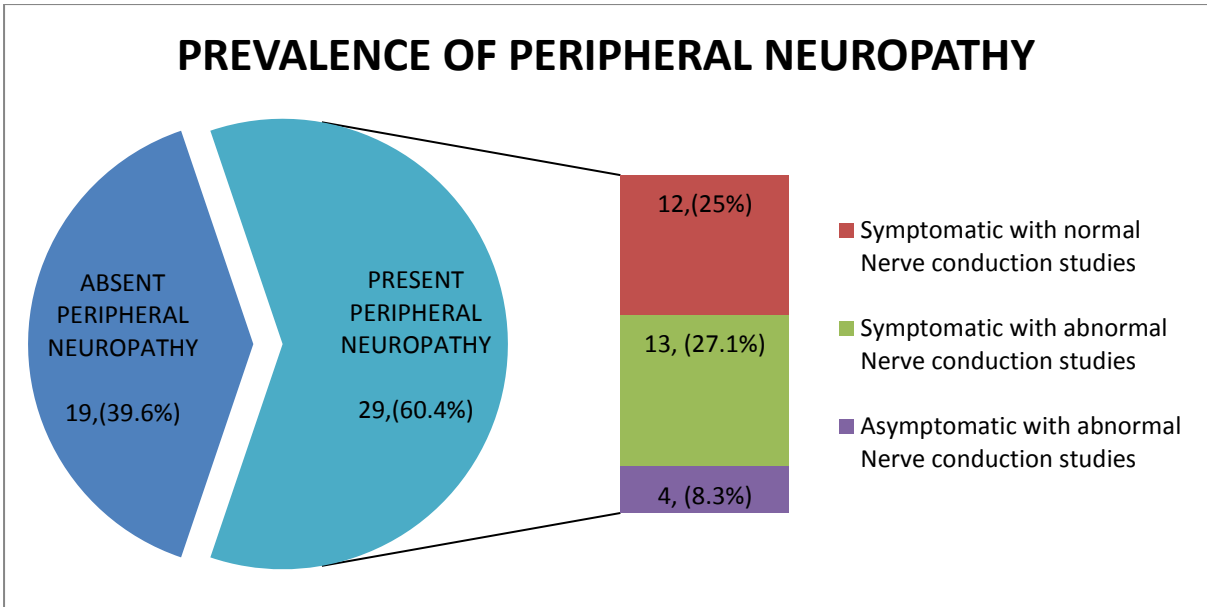
Hydroxychloroquine was the most commonly used disease modifying agents at 97.9%, with 38.46 months being the mean duration of usage. None of the patients were on cyclosporine and biological agents. 27.1 % of patients were on NSAIDS for pain management at a mean duration of usage of 27.1 months as outlined in table 3. Some patients were on more than one disease medication.

**Table 3: Medications taken by study participants n= 48**

<b>MEDICATION</b>	<b>YES (%)</b>	<b>Mean duration of Treatment (months)</b>	<b>SD</b>
<b>NSAIDs</b>	17.1	27.27	32.98
<b>HCQ</b>	97.9	38.46	38.59
<b>Leflunomide</b>	4.2	43.5	40.31
<b>MTX</b>	14.6	24.86	31.46
<b>Cyclosporine</b>	0	0	0
<b>MMF</b>	25.0	24.19	15.90
<b>AZA</b>	37.5	35.24	46.85
<b>Steroids</b>	85.4	41.9	42.21
<b>Biologics</b>	0	0	0

### 5.2Prevalence of Peripheral Neuropathy

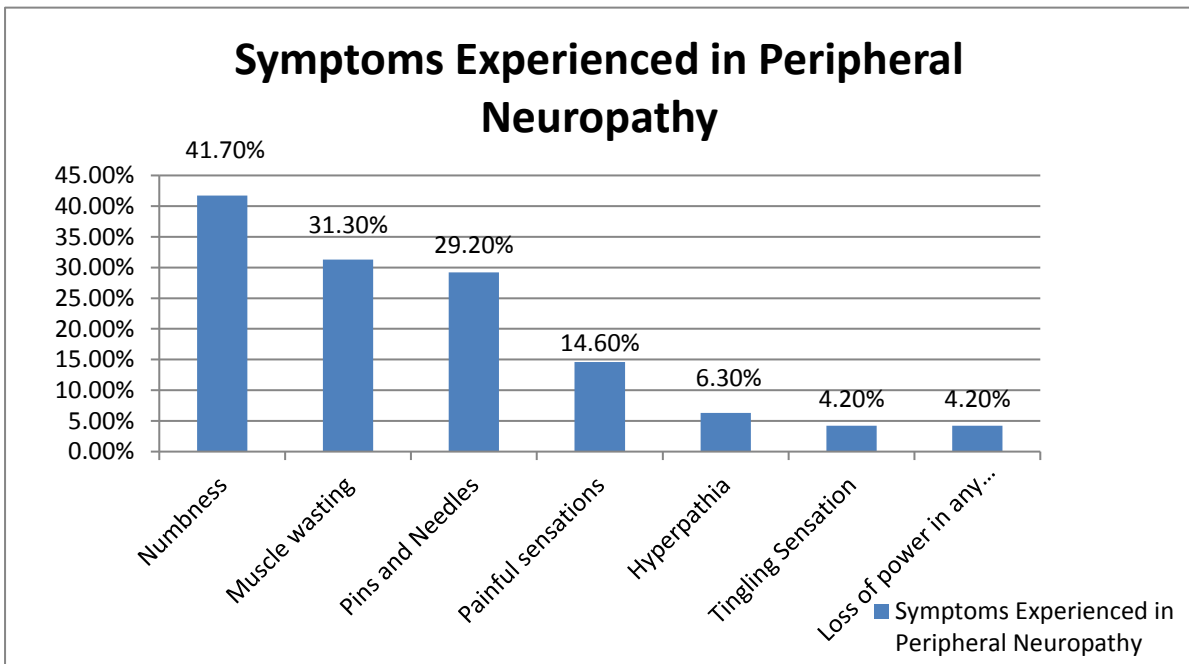
This population had an overall prevalence of peripheral neuropathy at 60.4%. Twenty seven point one percent of these had abnormal nerve conduction studies and were symptomatic for peripheral neuropathy while 25 % had normal nerve conduction studies despite being symptomatic for peripheral neuropathy. Whereas 8.3 % were asymptomatic and had abnormal nerve conduction studies as shown in figure 2.



**Figure 2: Prevalence of Peripheral Neuropathy and its presentation in the study participants (Sample population N=48)**

#### 5.2.1 Peripheral neuropathy symptoms experienced

Various frequencies of the neurological symptoms experienced at the time of presentation are depicted in figure 3. Numbness was the most common symptom complaint at 41.7%. In terms of the symptoms, some patients had more than one complaint.



**Figure 3: Symptoms experienced in peripheral neuropathy in the study population**

### **5.2.2 Sensory and Motor system examination findings**

3 patients had impaired touch sensation, 2 had impaired in vibration and 3 had impaired proprioception. There were no cases presenting with impaired pain and temperature sensation. In motor system findings, 3 patients had reduced muscle power and tone of the limbs and reduced reflexes.

## **5.3: Electrophysiological Types Of Peripheral Neuropathy**

### **5.3.1 Nerve conduction pathologies**

In this study, Demyelination was the most frequent nerve conduction pathology found among participants at a prevalence of 9(52.9%) out of 17 participants found to have abnormal nerve conduction studies. However 5 patients were found to have carpal tunnel syndrome, therefore on excluding them, then the prevalence of demyelination was detected to be much lower with 4(23.5%) study participants affected. Axonopathy was detected in 5(29.4%) of the study participants (n=17) as depicted in table 4.

### **5.3.2 Nerve conduction syndromes**

The most frequent type of nerve conduction syndrome detected among the study participants was Motor neuropathy with 9(52.9%) patients affected (n=17). as shown table 4. Carpal tunnel syndrome was detected in 5(29.4%) of the study participants (n=17). No patient had mononeuritis multiplex as outlined in table 4.

**Table 4: Electrophysiological types of Peripheral neuropathy in the study participants**

<b>Electrophysiological Types</b>	<b>Variables</b>	<b>Frequency n=17</b>	<b>Percent (%)</b>
<b>Nerve conduction pathologies</b>	Demyelination	9	52.9%
	Axonopathy	5	29.4%
	Axonopathy & Demyelinating	3	17.7%
<b>Nerve conduction syndromes</b>	Motor	9	52.9%.
	Sensory- motor	5	29.4%
	Sensory	3	17.37%
	Mononeuropathy	8	47.1%
	Mono-neuritis multiplex	-	-
	Carpal Tunel Syndrome	5	29.4%

Nine patients (52.9%) out of 17 were found to have a demyelinating type of peripheral neuropathy. Of these, 7 had motor demyelination and the other 2 had sensorimotor demyelination.

Five patients out of 17 (29.4%) were found to have axonopathic type of peripheral neuropathy. Of these, 2 had a sensory type of axonopathy, 2 had a motor type and 1 had sensorimotor type of axonopathy.

Three patients out of 17 (17.7%) had a combined axonopathy and demyelinating type of peripheral neuropathy. Of these, one (1) had a sensory type, and the other two (2) had sensorimotor peripheral neuropathy.



**Table 5 : Nerve Conduction Parameters in the study participants**

	Normal nerve conduction		Abnormal nerve conduction	
	Median	SD	Median	SD
<b>Nerve / CV</b>				
Motor Median	43	5.9	42.1	8.1
Motor Ulna	47.6	6.5	42.9	4.4
Motor Tibial	31.4	3.4	32.0	4.0
Motor Peroneal	36.8	2.4	35.0	3.9
<b>Nerve / Amplitude</b>				
Motor Median	12.4	3.0	12.1	5.0
Motor Ulna	10.6	2.5	10.6	4.1
Motor Tibial	10.1	3.7	5.9	4.1
Motor Peroneal	5.6	3.0	5.2	3.1
<b>Nerve / Latency</b>				
Motor Median	3.2	0.5	3.8	0.7
Motor Ulna	2.5	0.7	2.7	0.3
Motor Tibial	6.0	0.5	6.2	0.9
Motor Peroneal	4.1	0.6	4.2	1.3
<b>Nerve / F response</b>				
Motor Median	28.2	2.6	28.8	1.5
Motor Ulna	29.1	3.1	30.0	3.3

	<b>Normal nerve conduction</b>		<b>Abnormal nerve conduction</b>	
	<b>Median</b>	<b>SD</b>	<b>Median</b>	<b>SD</b>
<b>Sensory / CV</b>				
Sensory Median	57.2	7.6	51.3	7.9
Sensory Ulna	53.3	3.4	53.9	5.7
Sensory Sural	51.9	8.0	49.4	17.4
<b>Nerve / Amplitude</b>				
Sensory Median	25.3	11.2	24.4	12.5
Sensory Ulna	19.0	10.6	24.1	11.9
Sensory Sural	13.0	4.7	12.4	16.7
<b>Nerve / Latency</b>				
Sensory Median	2.4	0.4	2.7	0.5
Sensory Ulna	2.2	0.2	2.1	0.2
Sensory Sural	2.9	0.5	3.4	1.1

## 5.4 Quality Of Life

The health related quality of life was determined using the LUPUS QOL questionnaire. The mean raw domain score was transformed to scores ranging from 0 (worst HRQoL) to 100 (best HRQoL). There was generally an impaired overall score in the quality of life in all the six domains among our study participants. Physical health was the domain with the lowest score at (59.1%). Table 6 outlines summary of the findings.

**Table 6: LUPUS QOL score of study population n=48**

<b>Transformed Domain</b>	<b>Median (IQR)</b>
Physical health	59.1 (53.1)
Emotional health	75.0 (33.3)
Pain	75.0 (29.3)
Planning	75.0 (58.3)
Fatigue	68.8 (37.5)
Burden to others	75.0 (23.3)

## 5.5 ASSOCIATIONS

The correlations between Quality of life components on the domains of Physical health, pain, planning and burdens to others were statically significant as outlined on Table 7 below, on the univariate analysis however not significant on multivariate analysis as depicted on the table 8 below.

**Table7: Association of Peripheral Neuropathy with quality of life of patients in the study**

Variable	Peripheral Neuropathy		$\chi^2$	Odds ratio	P value
	Yes n=29 (%)	No n=19 (%)			
Physical health (<80)	21 (72.4%)	4 (21.1%)	12.13	9.84	<u>&lt;0.001</u>
Emotional health (<80)	19 (65.5%)	9 (47.4%)	1.66	2.11	0.212
Pain (<80)	15 (51.7%)	3 (15.8%)	6.32	5.71	<u>0.012</u>
Planning (<80)	17 (58.6%)	3 (15.8%)	8.66	7.56	<u>0.003</u>
Fatigue (<80)	20 (69.0%)	11 (57.9%)	0.62	1.62	0.433
Burden to others (<80)	19 (65.5%)	11 (57.9%)	8.01	11.10	<u>0.005</u>

\* $\chi^2$  Chi Square results (Pearson's) on R software

\*Significant associations are underlined in the table

**Table 8 : Multivariate analysis (Logistic Regression) of Peripheral Neuropathy with quality of Life in the study patients .**

	B	S.E.	Wald	Sig.	OR	95% C.I. for OR	
						Lower	Upper
Physical health(<80)	1.866	1.03	3.27	0.07	6.46	0.86	48.85
Pain (<80)	0.889	1.05	0.72	0.40	2.43	0.31	19.13
Planning (<80)	0.633	1.32	0.23	0.63	1.88	0.14	25
Burden (<80)	-1.08	0.87	1.54	0.22	0.34	0.06	1.874
Constant	-0.27	0.57	0.22	0.64	0.77		

## **6.0 CHAPTER SIX**

### **DISCUSSION**

The entire study population was made up of female participants. This is in keeping with most of the studies done locally in Kenya that reported a female predominance of between 95.2% to 97% (14–16,66,67).

The mean age of the study participants was 37.9 years, with the youngest patient at 18 years whereas the oldest was 60 years. This was comparable to other studies done on SLE patients locally in Kenya, Genga et al found a mean age of 36.6 years, Odhiambo et al found 37.3 years, Njoroge et al found 36.4 years and Conteh et al found 36.7 years (14–16,65). Therefore our study population consisted predominantly of young females in their reproductive age groups. This could be explained by the role of hormonal factors in the pathogenesis of SLE disease as described by Costenbader et al who associated the use of exogenous hormones with lupus onset and flares (68).

The most common drugs used in lupus treatment were hydroxychloroquine at (97.9%) followed by steroids at 85.4% these findings were similar to studies done locally (15,66). The inclination to use of HCQs can be attributed to its use being universally recommended in the guidelines, its affordability in our set up and its justified benefits in SLE. The high steroid use probably is because most of patients could have had active disease which is treated with steroids.

#### **6.1 Prevalence of Peripheral Neuropathy**

In this population of SLE patients, the overall prevalence of peripheral neuropathy was found to be high at 60.4%, with 29 out of the 48 patients affected. In our study, the prevalence of peripheral neuropathy among SLE patients was higher than those that had been done worldwide in Asia and in Europe. Saigal et al reported a prevalence of 36% (18 out of 50 patients), after defining Peripheral neuropathy electrophysiologically, therefore including patients who were symptomatic with abnormal nerve conduction studies as well as those who were asymptomatic with abnormal nerve conduction studies. However the study did not include those patients who were symptomatic for peripheral neuropathy and were found to have normal nerve conduction study, unlike our study that defined Peripheral neuropathy both clinically and electrophysiologically (49).

In a study done by Khean et al, a high prevalence of 56%(28 out of 50%) was detected in patients with SLE and they were found to have abnormal nerve conduction studies .This was because their study population was mainly composed of in patients hence external nerve compression in bed ridden patients, unlike our study that looked at ambulatory out patients attending rheumatology out patient clinic(50). Brundusa et al reported a prevalence of 14%. This low prevalence could be attributed by defining peripheral neuropathy clinically as per the ACR nomenclature and case definition of Neuropsychiatric manifestation of SLE and electrophysiologic studies only performed on patients who had muscle weakness(54). Unlike the other studies that defined peripheral neuropathy either electrophysiological only or clinically only, our study defined peripheral neuropathy both clinically and electrophysiologically therefore yielding a high prevalence of peripheral neuropathy. The high prevalence of peripheral neuropathy in our study could also be explained by the late presentation of SLE patients in our set up and also our patients could have had a high disease activity index , which studies have found to correlate with the presence of peripheral neuropathy, though our study did not assess for disease activity index (49,54). Racial difference with genetic variability on various studies may also explain the wide discrepancy on the prevalence of peripheral neuropathy as most studies were conducted in Europe, Asia and America. There was paucity of similar studies done in Africa.

Twelve patients (25%) with symptomatic peripheral neuropathy in our study were found to have normal nerve conduction studies; this probably represent patients who may have involvement of small diameter nerve fiber that is not picked on nerve conduction studies and these patients would benefit from either skin or nerve biopsy for confirmatory diagnosis. These results were similar to other studies done by Oomatia et al who found that 17.1% of SLE patients with peripheral neuropathy( 14 out of 82) had small fiber neuropathy, which is a painful neuropathy with normal nerve conduction studies , and not included in the 1999 American College of Rheumatology Neuropsychiatric SLE case definitions (40). Lasse G et al similarly evaluated small diameter nerve fiber neuropathy by taking skin biopsy and found a prevalence of 13% of SLE patients having involvement of small fiber diameter (41).

Thirteen patients (27.1%)with symptomatic peripheral neuropathy, had abnormal nerve conduction studies .This was similar to a study by Saigal et al in North asia where they found that 9 out of 18 patients with SLE were symptomatic for peripheral neuropathy and had nerve conduction study abnormality hence clinical peripheral neuropathy(49).

The remaining 4 patients (8.3%) in our study were asymptomatic and had abnormal nerve conduction studies, and represented a group of patients with subclinical peripheral neuropathy. This was almost similar to Saigal et al who found that 9 out of 18 patients with peripheral neuropathy had subclinical peripheral neuropathy(49).

## **6.2 Clinical features and symptoms of peripheral neuropathy in SLE**

The most common presenting symptoms of peripheral neuropathy in SLE in our study was numbness at 42.6% , followed by muscle wasting at 31.9% and pins and needle sensations at 29.8%. Loss of muscle power was at 4.3%. These findings were similar to other studies done worldwide by R Jasmin et al who described that numbness and tingling sensation was the most common symptoms experienced at 35.3% , while “ feeling weak” was reported at 8% (55). Yu ji su et al found that numbness was among the most frequent symptom of peripheral neuropathy in SLE patients(48).

In our study 3 patients had impairment to touch and proprioception while 2 patients had impairment to vibration. 3 patients had reduced distal muscle power of lower limbs and upper limbs and reduced reflexes. These findings were almost similar to that was observed by Saigal et al where they had reported 1 patient to have diminished deep tendon reflexes and 8 patients had varied intensity of diminished perception to touch, pain, temperature and vibration(49).

## **6.3 Electrophysiological Types of Peripheral Neuropathy**

### **6.3.1 Nerve conduction pathologies**

In our study, demyelination was found to be the most common type of nerve conduction pathology with 9 patients (59.9%) affected. In contrast to other studies done that found axonopathy to be the most common type of peripheral neuropathy (49,50,54). However, on excluding 5 patients with carpal tunnel syndrome, then the prevalence of demyelination was found to be 4(8.33%) in this study, therefore similar findings to the other studies that did not include carpal tunnel syndrome.

Five ( 29.4%) patients had axonopathy hence suggestive of vasculitic neuropathy as expected to occur in patients with SLE and this was consistent with what was found in previous studies(49).

### **6.3.2 Nerve Conduction Syndromes**

Most of our patients had 9 (52.9%) had motor neuropathy as the most common type of peripheral neuropathy. This was similar to a study done by Renu saigal et al who found that electrophysiological motor nerve parameters were frequently abnormal compared to sensory parameters , therefore SLE neuropathy was predominantly Motor neuropathy rather than sensory (49).

Five patients (29.4%) had Carpal Tunnel Syndrome, which is mononeuropathy of the median nerve, representing patients who could have has active SLE disease with Inflammation of wrist joint.

### **6.4 Peripheral neuropathy correlations**

The presence of peripheral neuropathy could have led to poor quality of life as concern the domains in Physical health, pain, planning and burdens to others. These findings were similar to a study by B. Florica who found that patients with peripheral neuropathy had significantly lower SF 36 score especially in the physical components , hence poor quality of life(54).



## **7.0 SUMMARY**

This study demonstrates a high prevalence of peripheral neuropathy among SLE patients. Its presentation varies both clinically and electrophysiologically. Small fiber neuropathy which presents with symptoms and normal nerve conduction studies is rather a common finding in SLE patients in our population. The proportion of patients with demyelination were substantially high however excluding patients with carpal tunnel syndrome then axonopathy was rather a common finding. Motor neuropathy, was more prevalent. There was no significant association of peripheral neuropathy with age groups, duration since diagnosis and drug treatment modalities. However there was a correlation of presence of peripheral neuropathy with quality of life as concerns domains in physical health, pain, planning and burdens to others.

## **8.0 CONCLUSION**

There is a high prevalence of peripheral neuropathy among SLE patients, with variable clinical and electrophysiologic presentation. Quality of life is scores are lower in affected patients

## **9.0 STUDY LIMITATION**

We were unable to exclude all confounding causes of peripheral neuropathy in our population due to resource limitation.

We were unable to perform sural nerve biopsy and skin punch Biopsy to further characterize the neuropathies in instances where nerve conduction study was non-revealing, due to financial constraints.

Electromyogram was not conducted in our study due to time and resource limitation.

This was a hospital based study therefore not generalizable.

## **10.0 RECOMMENDATIONS**

1. A prospective study to determine the progression and outcome of Peripheral neuropathy seen in SLE patients in our setting.
2. Skin and Nerve biopsy to be included in future studies especially in instances where nerve conduction studies were none revealing.
3. Electromyogram to be incorporated in subsequent studies for confirmatory diagnosis of radiculopathy
4. Base line symptom screen for peripheral neuropathy in all SLE patients

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## 12.0 APPENDICES

### 12.1 AppendixI:

#### SLICC CLASSIFICATION CRITERIA FOR SYSTEMIC LUPUS ERYTHEMATOUS

Requirements: more than 4 criteria (at least 1 clinical and 1 laboratory criteria) or biopsy – proven lupus nephritis with positive ANA or Anti-DNA

<b>Clinical Criteria</b>	<b>Immunological Criteria</b>
Acute cutaneous Lupus	ANA
Chronic cutaneous Lupus	Anti-DNA
Oral or Nasal Ulcers	Anti-Sm
Non-scarring alopecia	Antiphospholipid antibodies
Arthritis	Low complement ( C3, C4, CH50)
Serositis	Direct combs' test
Renal	
Neurological	
Hemolytic Anemia	
Leukopenia	
Thrombocytopenia( < 100,000/mm <sup>3</sup> )	

### 12.2 AppendixII:

#### **Neuropsychiatric Syndromes In Systemic Lupus Erythematosus**

<b>Central</b>	<b>Peripheral</b>
Aseptic meningitis	Guillain-Barre syndrome
Cerebrovascular disease	Autonomic neuropathy
Demyelinating syndrome	Mononeuropathy
Headache	Myasthenia gravis
Movement disorder	Cranial neuropathy
Seizure disorder	Plexopathy
Myelopathy	Polyneuropathy
Acute confusional state	
Anxiety disorder	
Cognitive dysfunction	
Mood disorder	
Psychosis	

*Adapted from: The American College of Rheumatology nomenclature and case definitions for neuropsychiatric lupus syndromes. Arthritis Rheum 1999; 42:59*



**12.3 AppendixIII: Study Proforma**

**QUESTIONNAIRRE**

**PARTICIPANTS STUDY NUMBER** \_\_\_\_\_

**1. SOCIO - DEMOGRAPHIC CHARACTERISTICS( tick / fill where appropriate)**

SEX: M ( ) F ( )

AGE ( ) YEARS

OCCUPATION.....

RESIDENCE\_\_\_\_\_

MARRIED ( ) SINGLE ( ) DIVORCED ( ) SEPARATED ( )

**2. ANTHROPOMETRIC MEASURES (Fill in the values)**

Height (cm) .....

Weight (Kg) .....

BMI .....

**3. HAVE YOU BEEN TREATED FOR THESE MEDICAL CONDITIONS IN THE PAST?(tick where appropriate)**

T.B ( ) EPILEPSY ( )

PINS AND NEEDLES ( )

ANAEMIA ( ) BURNING SENATION ( )

PARALYSIS ( ) KIDNEY FAILURE ( )

PARAESTHESIAE ( )

**4. HAVE YOU BEEN ON TREATMENT WITH THESE DRUGS?(tick where appropriate)**

Drug	History of Usage		If Yes Duration
	Yes	No	
NSAIDS			
Hydroxoychloroquine			
Leflunomide			
Methotrexate			
Cyclosporine			
Mycophenolatemofetil			
Azathioprine			
Steroids			

Biologic agents			
-----------------	--	--	--

**5. WHAT IS THE DURATION SINCE YOU WERE DIAGNOSED TO HAVE SLE?( Fill in details)**

( ) days ( ) months ( ) years

**6. DO YOU EXPERIENCE THE SYMPTOMS PERIPHERAL NEUROPATHY BELOW? (tick where appropriate)**

- PINS AND NEEDLES ( )
- HYPERPATHIA ( )
- LOSS OF PAIN SENSATION ( )
- LOSS OF TEMP SENSATION ( )
- TINGLING SENSATION ( )
- NUMBNESS ( )
- PAINFUL SENSATION ( )
- LOSS OF TOUCH SENSATION ( )
- MUSCLE WASTING ( )
- LOSS OF POWER IN ANY LIMB ( )

**7. PHYSICAL EXAMINATION FINDINGS ON SIGNS OF PERIPHERAL NEUROPATHY (tick/fill in where appropriate)**

- Impaired Sensation

Touch ( ) Pain ( ) Vibration ( ) Temperature ( ) Proprioception ( )

- Muscle group examination

<b>MUSCLES</b>	<b>TONE</b>	<b>POWER</b>
Ankle Flexors	( )	( )
Ankle Extensors	( )	( )
Knee Flexors	( )	( )
Knee Extensors	( )	( )
Hip Flexors	( )	( )
Hip Extensors	( )	( )
Hand Grip	( )	( )
Elbow Extensors	( )	( )
Elbow Flexors	( )	( )
Shoulder Joint Extensors	( )	( )
Shoulder Joint Flexors	( )	( )
Shoulder adductors	( )	( )
Shoulder abductors	( )	( )

- Examination of Reflexes

<b>TENDON</b>	<b>NORMAL</b>	<b>INCREASED</b>	<b>DECREASED</b>
<b>REFLEXES</b>			
Ankle	( )	( )	( )
Knee	( )	( )	( )
Triceps	( )	( )	( )
Biceps	( )	( )	( )
Plantar Reflex	Flexor ( )	Extensor ( )	

**8. NERVE CONDUCTION STUDIES( fill in details)**

**• MOTOR NERVES**

<b>Nerves</b>	<b>CV(m/s)</b>	<b>Amplitude(Mv)</b>	<b>Latency(ms)</b>	<b>F-response (ms)</b>
Median				
Ulnar				
Tibial				
Peroneal				

**• SENSORY NERVES**

<b>Nerves</b>	<b>CV(m/s)</b>	<b>Amplitude(Mv)</b>	<b>Latency (ms)</b>
Median			
Ulnar			
Sural			

## **12.4 Appendix IV: Lupus QOL Questionnaire**

### **LupusQOL Questionnaire**

The following questionnaire is designed to find out how SLE affects your life. **Read** each statement and then **circle** the response, which is **closest to how you feel**. Please try to answer all the questions as honestly as you can.

#### **How often over the last 4 weeks**

**1. Because of my Lupus I need help to do heavy physical jobs such as digging the garden, painting and/or decorating, moving furniture**

All of the time, most of the time, a good bit of the time, occasionally, never

**2. Because of my Lupus I need help to do moderate physical jobs such as vacuuming, ironing, shopping, cleaning the bathroom**

All of the time, most of the time, a good bit of the time, occasionally, never

**3. Because of my Lupus I need help to do light physical jobs such as cooking/preparing meals, opening jars, dusting, combing my hair or attending to personal hygiene**

All of the time, most of the time, a good bit of the time, occasionally, never

**4. Because of my Lupus I am unable to perform everyday tasks such as my job, childcare, housework as well as I would like to**

All of the time, most of the time, a good bit of the time, occasionally, never

**5. Because of my Lupus I have difficulty climbing stairs**

All of the time, most of the time, a good bit of the time, occasionally, never

**6. Because of my Lupus I have lost some independence and am reliant on others**

All of the time, most of the time, a good bit of the time, occasionally, never

**7. I have to do things at a slower pace because of my Lupus**

All of the time, most of the time, a good bit of the time, occasionally, never

**8. Because of my Lupus my Sleep pattern is disturbed**

All of the time, most of the time, a good bit of the time, occasionally, never

**How often over the last 4 weeks**

**9. I am prevented from performing activities the way I would like to because of pain due to Lupus**

All of the time, most of the time, a good bit of the time, occasionally, never

**10. Because Of My Lupus, the pain I experience interferes with the quality of my Sleep**

All of the time, most of the time, a good bit of the time, occasionally, never

**11. The pain due to my Lupus is so severe that it limits my mobility**

All of the time, most of the time, a good bit of the time, occasionally, never

**12. Because of my Lupus I avoid planning to attend events in the future**

All of the time, most of the time, a good bit of the time, occasionally, never

**13. Because of the unpredictability of my Lupus I am unable to organize my life efficiently**

All of the time, most of the time, a good bit of the time, occasionally, never

**14. My Lupus varies from day to day which makes it difficult for me to commit myself to social arrangements**

All of the time, most of the time, a good bit of the time, occasionally, never

**15. Because of the pain I experience due to Lupus I am less interested in a sexual relationship**

All of the time, most of the time, a good bit of the, occasionally, never, not applicable

**16. Because of my Lupus I am not interested in sex**

All of the time, most of the time, a good bit of the time, occasionally, never .not applicable

**17. I am concerned that my Lupus is stressful for those who are close to me**

All of the time, most of the time, a good bit of the time, occasionally, never

**18. Because of my Lupus I am concerned that I cause worry to those who are close to me**

All of the time, most of the time, a good bit of the time, occasionally, never

**19. Because of my Lupus I feel that I am a burden to my friends and/or family**

All of the time, most of the time, a good bit of the time, occasionally, never

**Over the past 4 weeks I have found my Lupus makes me**

**20. Resentful**

All of the time, most of the time, a good bit of the time, occasionally, never

**21. So fed up nothing can cheer me up**

All of the time, most of the time, a good bit of the time, occasionally, never

**22. Sad**

All of the time, most of the time, a good bit of the time, occasionally, never

**23. Anxious**

All of the time, most of the time, a good bit of the time, occasionally, never

**24. Worried**

All of the time, most of the time, a good bit of the time, occasionally, never

**25. Lacking in self-confidence**

All of the time, most of the time, a good bit of the time, occasionally, never

**How often over the past 4 weeks**

**26. My physical appearance due to Lupus interferes with my enjoyment of life**

All of the time, most of the time, a good bit of the time, occasionally, never

**27. Because of My Lupus, my appearance (e.g. rash, weight gain/loss) makes me avoid social situations**

All of the time, most of the time, a good bit of the time, occasionally, never, not applicable

**28. Lupus related skin rashes make me feel less attractive**

All of the time, most of the time, a good bit of the time, occasionally, Never, not applicable

**How often over the past 4 weeks**

**29. The hair loss I have experienced because of my Lupus makes me feel less attractive**

All of the time, most of the time, a good bit of the time, occasionally, never, not applicable

**30. The weight gain I have experienced because of my Lupus treatment makes me feel less attractive**

All of the time, most of the time, a good bit of the time, occasionally, never, not applicable

**31. Because of my Lupus I cannot concentrate for long periods of time**

All of the time, most of the time, a good bit of the time, occasionally, never

**32. Because of my Lupus I feel worn out and sluggish**

All of the time, most of the time, a good bit of the time, occasionally, never

**33. Because of my Lupus I need to have early nights**

All of the time, most of the time, a good bit of the time, occasionally, never

**34. Because of my Lupus I am often exhausted in the morning**

All of the time, most of the time, a good bit of the time, occasionally, never

**Please feel free to make any additional comments.**

.....  
.....  
.....

**Please check that you have answered each question**

**Thank you, for completing this questionnaire**



## **KIWAHILI: LUPUS QUALITY OF LIFE QUESTIONAIRE**

### **Swali la Lupus QOL**

Jarida lafuatayo linaloundwa ili kujua jinsi SLE huathiri maisha yako. Soma kila kielelezo na kisha uzunguruze majibu, ambayo ni karibu na jinsi unavyohisi. Tafadhali jaribu kujibu maswali yote Kwa uaminifu iwezekanavyo.

### **Mara ngapi zaidi ya majuma nne (4) iliyopita**

**1. Kwa sababu ya Lupus yangu ninahitaji msaada wa kufanya kazi nzito za kimwili kama vile kuchimba bustani, uchoraji na / au mapambo, samani zinazohamia**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**2. Kwa sababu ya Lupus yangu ninahitaji msaada wa kufanya kazi za kawaida za kimwili kama vile kufuta, kupiga nguo pasi, ununuzi, kusafisha bafuni**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**3. Kwa sababu ya Lupus yangu ninahitaji msaada wa kufanya kazi za kimwili kama vile kupika / kuandaa chakula, kufungua mitungi, kutoa vumbi, kuchana nywele zangu au kuhudhuria usafi wa kibinafsi**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**4. Kwa sababu ya Lupus yangu siwezi kufanya kazi za kila siku Kama vile kazi yangu ya kawaida, huduma za watoto, kazi za nyumbani Kama vile ninavyopenda**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**5. Kwa sababu ya Lupus yangu nina shida kupanda ngazi**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**6. Kwa sababu ya Lupus yangu nimepoteza uhuru wangu na ninategemea wengine**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**7. Ninafanya mambo kwa kasi ndogo kwa sababu ya Lupus yangu**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**8. Kwa sababu ya Lupus yangu ruwaza yangu ya usingizi inasumbuliwa**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**Mara ngapi zaidi ya majuma nne(4) iliyopita**

**9. Ninazuiliwa kufanya shughuli Kama vile napenda kwa sababu ya maumivu kutokana na Lupus**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**10. Kwa sababu ya Lupus yangu, maumivu ninayopata yanaathiri ubora wa usingizi wangu**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**11. Maumivu yanayotokana na Lupus yangu ni kali kiasi kwamba inaleta mipaka kwa uhamaji wangu.**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**12. Kwa sababu ya Lupus yangu mimi huepuka kupanga mipango ya kuhudhuria matukio katika siku zijazo**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**13. Kwa sababu ya kutokuwa na uhakika wa Lupus yangu siwezi kuandaa maisha yangu kwa ufanisi**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**14. Lupus yangu inatofautiana kila siku ambayo inifanya vigumu kwangu kujitolea kwenye mipangilio ya kijamii**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**15. Kwa sababu ya maumivu niliyoyapata kwa sababu ya Lupus mimi sina nia ya uhusiano wa ngono**

Wakati wote, wakati mwingi, muda mzuri, mara kwa mara, kamwe, haifai

**16. Kwa sababu ya Lupus yangu mimi sina nia ya ngono**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe. Haitumiki

**17. Nina wasiwasi kwamba Lupus yangu inawahangaisha wale walio karibu nami**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**18. Kwa sababu ya Lupus yangu nina wasiwasi kwamba ninawahangaika wale walio karibu nami**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**19. Kwa sababu ya Lupus yangu ninahisi kuwa mimi mzigo kwa marafiki zangu na / au familia**

Wakati wote, mara nyingi, wakati mzuri, mara kwa mara, kamwe

**Zaidi ya wiki nne(4) zilizopita nimepata Lupus yangu inanifanya**

**20. Hasira**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**21. Kuchoka hakuna kinachoweza kunifurahisha**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**22. Kutokuwa na furaha**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**23. wasiwasi**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**24. wasiwasi**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**25. Kutokuwa na kujiamini**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**Mara ngapi zaidi ya wiki nne(4) zilizopita**

**26. Muonekano wangu wa kimwili kutokana na Lupus huingilia furaha yangu ya maisha**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**27. Kwa sababu ya Lupus Yangu, kuonekana kwangu (kama. Mwili kupasuka, uzito / kupoteza uzito) kunifanya kuepuka hali za kijamii**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe, hauhusiani

**28. Lupus kuhusiana na ngozi hufanya mimi kujisikia chini ya kuvutia**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, Kamwe, haipatikani

**Mara ngapi zaidi ya wiki nne (4) zilizopita**

**29. Upotevu wa nywele niliyopata kwa sababu ya Lupus yangu hufanya nihisi chini ya kuvutia**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe, hauhusiani

**30. Uzito wa mwili niliyopata kwa sababu ya matibabu yangu ya Lupus hufanya mimi kujisikia chini ya kuvutia**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe, hauhusiani

**31. Kwa sababu ya Lupus yangu siwezi kuzingatia kwa muda mrefu**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**32. Kwa sababu ya Lupus yangu ninajisikia nimechoka na mvivu**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**33. Kwa sababu ya Lupus yangu ninahitaji kuwa na usiku wa mapema**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

**34. Kwa sababu ya Lupus yangu mimi mara nyingi nimechoka asubuhi**

Wakati wote, mara nyingi, muda mzuri, mara kwa mara, kamwe

Tafadhali jisikie huru kufanya maoni yoyote ya ziada.

.....  
.....  
.....  
.....

Tafadhali angalia kwamba umejibu kila swali

Asante, kwa kukamilisha safari hii

## 12.5 AppendixV: Nerve Conduction Study Reference Ranges(65).

### **MOTOR NERVES**

#### **Median Nerve**

Conduction Velocity	$\geq 49\text{m/s}$
Amplitude	$\geq 4.0\text{mv}$
Distal Latency	$\leq 4.4\text{ms}$
F response	$\leq 31\text{ms}$

#### **Ulnar Nerve**

Conduction Velocity	$\geq 49\text{m/s}$
Amplitude	$\geq 6.0\text{mv}$
Distal Latency	$\leq 3.3\text{ms}$
F response	$\leq 32\text{ms}$

#### **Tibial Nerve**

Conduction Velocity	$\geq 41\text{m/s}$
Amplitude	$\geq 4.0\text{mv}$
Distal Latency	$\leq 5.8\text{ms}$
F response	$\leq 56\text{ms}$

#### **Peroneal nerve**

Conduction Velocity	$\geq 44\text{m/s}$
Amplitude	$\geq 2.0\text{mv}$
Distal Latency	$\leq 6.5\text{ms}$
F response	$\leq 56\text{ms}$

### **SENSORY NERVES**

#### **Median Nerves**

Conduction Velocity	$> 50\text{m/s}$
Amplitude	$> 20\text{mv}$
Distal Latency	$< 3.5\text{ms}$

#### **Ulnar Nerve**

Conduction Velocity	$> 50\text{m/s}$
Amplitude	$> 17\text{mv}$
Distal Latency	$< 3.1\text{ms}$

#### **Sural Nerve**

Conduction Velocity	$\geq 40\text{m/s}$
Amplitude	$\geq 6.0\text{mv}$
Distal Latency	$\leq 4.4\text{ms}$

## 12.6 APPENDIX VI : NERVE CONDUCTION STUDIES PROCEDURE

- The nerves was stimulated proximally and distally at supramaximal current strength using an electronic stimulator type SEM 4101, at a current duration of 0.05 – 0.1 msec and a voltage of 100 – 200 volts. There was no discomfort in the procedure.
- The stimulator provided a trigger current that was used to trigger sweeps on the electromyography machine and the storage oscilloscope type 564B of TetronixInc, USA and was also equipped with a timer signal, which can be stored and reproduced by the oscilloscope. The response was fed into the electromyography through its pre-amplifier.
- The median and ulnar nerves were stimulated at the elbow and wrist for proximal and distal latencies respectively. The muscle action potentials of both were picked up by a single set of surface electrodes on the thenar eminence.
- The muscle action potential of the peroneal nerve was picked by similar electrodes placed on the extensor digitorum brevis and the nerve was stimulated at the head of the fibular and at the ankle.

### **For H-responses, the tibial nerve was used.**

- For the motor nerves or its components were assessed by stimulating the nerve electrically at two or more sites, and recording from the muscle innervated. The same electrical stimulation were done for sensory nerves or its components but the recording were done at another site on the stimulated nerve trunks.

## **12.7 Appendix VII: Participant Information and Consent Form**

### **Participant Information**

**Title of study:** Prevalence and electrophysiological types of peripheral neuropathy in patients with Systemic Lupus Erythematosus in Kenyatta National Hospital.

### **Principal Investigator/ and institutional affiliation:**

Dr. Wendo Cynthia Matilda Auma

Department of clinical medicine and therapeutics

University of Nairobi

P.O BOX 30197

GPO, Nairobi, Kenya

Tel: 0702490815

### **Co-Investigators and Institutional affiliation:**

1. Prof G. Omondi Oyoo

Department of clinical medicine and therapeutics

University of Nairobi

P.O BOX 30197

GPO, Nairobi, Kenya

2. Dr. T. O Kwasa

Department of clinical medicine and therapeutics

University of Nairobi

P.O BOX 30197

GPO, Nairobi, Kenya

3. Dr M. C Maritim

Department of clinical medicine and therapeutics

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P.O BOX 30197

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4. Dr Sybill Nakitare

Department of Medicine  
Kenyatta National Hospital  
P. O. BOX 20723 – 00202  
Nairobi, Kenya

5. Dr. Judith Kwasa

Department of clinical medicine and therapeutics  
University of Nairobi  
P.O BOX 30197  
GPO, Nairobi, Kenya

## **Introduction**

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol no. P633/11/2017.

## **WHAT IS THIS STUDY ABOUT?**

The researchers listed above are interviewing individuals who have Systemic Lupus Erythematosus. The purpose of the interview is to find out if they have Peripheral neuropathy, the type they have and their quality of life. Participants in this research study will be asked questions about symptoms of Peripheral neuropathy and will undergo physical examination in order to pick up the signs of peripheral neuropathy. They will also fill a questionnaire form on the quality of life. Participants will also have a choice to undergo tests such as Nerve conduction studies. There will be approximately 48 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

## **WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?**

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 20 minutes. The interview will cover topics such as information on your personal biodata such as age, gender, marital status and level of education. Your name and hospital number will not be included in this information for your privacy. Information on your Systemic Lupus Erythematosus disease diagnosis and treatment will be obtained and verified from your medical records. Details on symptoms of peripheral neuropathy and on quality of life will be enquired from you.

After the interview has finished, we shall carry out a physical examination on you to identify signs of peripheral neuropathy. Thereafter we shall proceed to do nerve conduction studies. This will be done outside KNH at the Neurology Center, which is situated in General Accident House on Ralph Bunche road in Nairobi. A nerve conduction study is a medical test used to evaluate the function of nerves in the body, and therefore diagnosing peripheral neuropathy and establishing the type of peripheral neuropathy. Needle electrode will be places over your skin in the area of the nerve to be tested and then activated electrically with small safe pulses, and the information will then be relayed into the machine measuring the responses obtained. The procedure will take approximately between 30 to 60 minutes. Decency will be maintained at all stages of this procedure.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include asking you to come for the nerve conduction studies in case it shall not be done on the same day for one reason or the other, and also giving you the results of the test findings and referring you to your doctor for further treatment if necessary according to the results.

## **ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?**

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting

your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

It may be embarrassing for you to have a physical examination conducted. We will do everything we can to ensure that this is done in a private room. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, event recall during the interview may be stressful.

You may feel some discomfort when placing the needle electrodes over your skin during the nerve conduction studies and you may have a small bruise or swelling in your skin. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary. The Electrode needles that will be used in the study will be sterilized and proper clean techniques will be followed in order to ensure no risk to the participants.

#### **ARE THERE ANY BENEFITS BEING IN THIS STUDY?**

You may benefit by receiving free Nerve conduction study testing .We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us improve clinical decision making and patient care in this unit. This information is a contribution to science and will assist in delivering expert clinical guidelines on screening of peripheral neuropathy in patients with Systemic Lupus Erythematosus.

#### **WILL BEING IN THIS STUDY COST YOU ANYTHING?**

This study will not cost you anything. All the costs pertaining this study including the nerve conduction study testing will be covered by the investigators.

#### **WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?**

If the study will not be done on the same day, the participants will be given some allowance to facilitate their return trip.

## **WHAT IF YOU HAVE QUESTIONS IN FUTURE?**

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh\_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

## **WHAT ARE YOUR OTHER CHOICES?**

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

## **CONSENT FORM (STATEMENT OF CONSENT)**

### **Participant's statement**

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

**I agree to participate in this research study: Yes No**

I agree to provide contact information for follow-up: Yes No

**Participant** \_\_\_\_\_ **printed** \_\_\_\_\_ **Name**  
: \_\_\_\_\_

**Participant signature / Thumb stamp** \_\_\_\_\_ **Date** \_\_\_\_\_

**Researcher's statement**

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

**Researcher's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signature**

\_\_\_\_\_

**Role in the study:** \_\_\_\_\_ *[i.e. study staff who explained informed consent form.]*

For more information contact Dr Wendo C A Matilda, Tel: 0702490815 at University of Nairobi, department of clinical medicine and therapeutics, from 8:00 am to 5:00pm.

Witness Printed Name *(If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant)*

**Name** \_\_\_\_\_ **Contact information** \_\_\_\_\_

**Signature /Thumb stamp:** \_\_\_\_\_ **Date;** \_\_\_\_\_

## **KISWAHILI: Maelezo ya Washiriki na Fomu ya Ruhusa**

### **Maelezo ya Washiriki**

**Jina la Utafiti:** Kiwango cha maambukizi na Ainaza ugonjwa wa neuropathy wa pembeni kwa wagonjwa wenye “Systemic Lupus Erythematosus” katika Hospitali ya Taifa ya Kenyatta.

### **Mtafiti Mkuu / ushirikiano wa taasisi:**

DR. Wendo Cynthia Matilda Auma

Idara ya dawa za kliniki na matibabu ,

Chuo Kikuu cha Nairobi

P.O BOX 30197

GPO, Nairobi, Kenya

Simu: 0702490815

### **Wachunguzi wa ushirikiano / ushirika wa taasisi:**

1. Prof G. Omondi Oyoo

Idara ya dawa za kliniki na matibabu

Chuo Kikuu cha Nairobi

P.O BOX 30197

GPO, Nairobi, Kenya

2. DR. T. O Kwasa

Idara ya dawa za kliniki na matibabu

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3. DR. M. C Maritim

Idara ya dawa za kliniki na matibabu

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1. Dr Sybill Nakitare

Idara ya Matibabu  
Hospitali Kuu ya Kenyatta  
P. O. BOX 20723 – 00202  
Nairobi, Kenya

2. Dr. Judith Kwasa

Idara ya dawa za kliniki na matibabu  
Chuo Kikuu cha Nairobi  
P.O BOX 30197  
GPO, Nairobi, Kenya

### **Utangulizi**

Ningependa kukuambia kuhusu utafiti utakayofanywa na watafiti waliotajwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji ili kukusaidia uamuzi au ikiwa ushiriki katika utafiti huo. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kinachotokea ikiwa unashiriki katika utafiti, hatari na faida iwezekanavyo, haki zako kama kujitolea, na kitu kingine chochote kuhusu utafiti au fomu hii ambayo haijulikani. Tunapojibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kuwa katika utafiti au la. Utaratibu huu unaitwa 'kibali cha habari'. Mara unapoelewa na kukubali kuwa katika utafiti, nitawaomba usaini jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumiwa kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni kikamilifu kwa hiari ii) Unaweza kujiondoa kwenye utafiti wakati wowote bila ya kutoa sababu ya uondoaji wako iii) Kukataa kushiriki katika utafiti haita-athiri huduma unazopata kwenye kituo hiki cha afya au vifaa vingine. Tutakupa nakala ya fomu hii kwa rekodi zako.

Naweza kuendelea? NDIO / LA

Utafiti huu una kibali ya Hospitali ya Taifa ya Kenyatta-Chuo Kikuu cha Nairobi Kamati za Utafiti na Maadili, Nambari: P633 / 11/2017.

**Utafiti huu ni nini?**



Watafiti waliotajwa hapo juu watahojiana na watu ambao wana ugonjwa wa "Systemic Lupus Erythematosus". Kusudi la mahojiano ni kujua kama wana ugonjwa wa "neuropathy ya pembeni", aina zao na ubora wa maisha. Washiriki katika utafiti huu wataulizwa maswali juu ya dalili za ugonjwa wa "neuropathy ya pembeni" na watajaribu kuchunguza kimwili ili kuchukua ishara za ugonjwa wa neuropathy ya pembeni. Pia watajaza fomu ya maswali ya ubora wa maisha. Washiriki pia watakuwa na chaguo la kupitia vipimo kama vile "Nerve conduction studies". Kutakuwa na washiriki takriban 48 katika utafiti huu kwa nasibu waliochaguliwa. Tunaomba ridhaa yako kufikiria kushiriki katika utafiti huu.

### **NINI KITAKACHOTOKEA IKIWA UNAAMUA KUWA KATIKA UTAFITI HUU?**

Ikiwa unakubali kushiriki katika somo hili, mambo yafuatayo yatatokea:

Utashughulikiwa na mhojiwaji mwenye ujuzi, katika eneo la kibinafsi ambako unajisikia kujibu maswali. Mahojiano itaendelea kwa dakika 20. Mahojiano yatakuja mada kama habari juu ya biodata yako binafsi, kama umri, jinsia, hali ya ndoa na kiwango cha elimu. Jina lako na nambari ya hospitali hazitajumuishwa katika habari hii kwa faragha yako. Taarifa juu ya utambuzi wako wa ugonjwa wa "Systemic Lupus Erythematosus" na matibabu yake utaulizwa kisha kuthibitishwa kwenye kumbukumbu zako za matibabu. Maelezo juu ya dalili za ugonjwa wa neuropathy ya pembeni na ubora wa maisha utaulizwa.

Baada ya mahojiano kumalizika, tutafanya uchunguzi wa kimwili juu yako ili kuchukua ishara za "neuropathy ya pembeni". Baadaye tutaendelea kufanya tafiti za "Nerve conduction studies" ambao utafanyika nje ya KNH katika Kituo cha Neurology, kilicho katika "General Accident house" hapa jijini Nairobi, Jumba leyewe liko "Ralph Buche Road". "Nerve conduction studies" ni utafiti uliotumika kutathmini kazi ya "nerve" katika mwili, na kwa hiyo kutambua upungufu wa "nerve" pembeni na kujua aina ya ugonjwa wa "neuropathy ya pembeni". "Electrode" ya sindano itakuwa mahali juu ya ngozi yako katika eneo la "Nerve" ya kupimwa na kisha kuanzishwa kwa umeme na vidonda vidogo vya salama, na habari hiyo itarejeshwa kwenye mashine ya electromyogram kupima majibu yaliyopatikana. Utaratibu huu utachukua dakika 30 hadi 60. Uamuzi utahifadhiwa katika hatua zote za utaratibu huu.

Tutaomba namba yako ya simu ambapo tunaweza kuwasiliana na wewe ikiwa ni lazima. Ikiwa unakubaliana kutoa maelezo yako ya mawasiliano, itatumiwa tu na watu wanaofanya kazi kwa ajili ya utafiti huu na kamwe hawatashirikiwa na wengine. Sababu ambazo tunaweza kuwasiliana na wewe ni pamoja na kuuliza wewe kuja kwa Utafiti wa "nerve conduction studies" ikiwa hautafanyika siku hio kwa sababu moja au nyingine, na pia kukupa

matokeo ya utafiti huo na kukutaja kwa daktari wako kwa matibabu zaidi ikiwa ni lazima kulingana na matokeo.

### **Je, kuna Hatari yoyote, madhara,na Usumbufu unaohusiana na Utafiti huu?**

Utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili. Jitihada zinapaswa kuwekwa daima ili kupunguza hatari. Hatari moja ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unachotuambia kama siri iwezekanavyo. Tutatumia nambari yautafiti ili kukutambua kwenye databana la kompyuta iliyohifadhiwa na nenosiri na kuhifadhi kumbukumbu zote za karatasi kwenye baraza la mawaziri lililofungwa. Hata hivyo, hakuna mfumo wa kulinda.

siri yako haiwezi kuwa salama kabisa, kwa hivyo bado inawezekana kwamba mtu anaweza kujua wewe ulikuwa katika utafiti huu na anaweza kupata maelezo kuhusu wewe.

Pia, kujibu maswali katika mahojiano inaweza kuwa na wasiwasi kwako. Ikiwa kuna maswali yoyote hautaki kujibu, unaweza kuruka. Una haki ya kukataa mahojiano au maswali yoyote yaliyoulizwa wakati wa mahojiano.

Inaweza kuwa aibu kwa wewe kuwa na uchunguzi wa kimwili unaofanywa. Tutafanya kila kitu tunaweza kuhakikisha kuwa hii inafanyika katika chumba cha faragha. Zaidi ya hayo, wafanyakazi wote wa utafiti na wahojiwa ni wataalamu wenye mafunzo maalum katika mitihani / mahojiano haya. Pia, kukumbuka tukio wakati wa mahojiano inaweza kuwa na shida.

Unaweza kujisikia wasiwasi wakati unapoweka electrodes ya sindano juu ya ngozi yako wakatiwa “nerve conduction studies” na huenda ukawa na uvimbe mdogo au uvimbe katika ngozi yako. Ikiwa kuna jeraha, magonjwa au matatizo yanayohusiana na utafiti huu, wasiliana na wafanyakazi wa utafiti huu mara moja kwa idadi iliyotolewa mwishoni mwa hati hii. Wafanyakazi wa kujifunza watawafanyia kwa hali ndogo au kukutaja wakati unaohitajika. Sindano za Electrode zitakazotumiwa katika utafiti zitatengenezwa na mbinu sahihi na njia za usafi zitafuatwa ili kuhakikisha hakuna hatari kwa washiriki.

### **Je, kuna faida yoyote kuwa katika utafiti huu?**

Unaweza kufaidika kwa kupata “nerve conduction study” kwa bure. Tutawapeleka kwenye hospitali kwa ajili ya utunzaji na msaada ikiwa inahitajika. Pia, maelezo unayoyotoa yatatusaidia kuboresha uamuzi wa kliniki na huduma ya mgonjwa katika kitengo hiki. Taarifa hii italeta mchango kwa sayansi na itasaidia kutoa miongozo ya kliniki ya mtaalam juu ya

uchunguzi wa ugonjwa wa neuropathy wa pembeni kwa wagonjwa wenye “Systemic Lupus Erythematosus”.

### **KUSHIRIKI KATIKA UTAFITI HUU UNADAI GHARAMA YOYOTE?**

Hautalipa chochote ku kushiriki kwa utafiti huu. Gharama zote zinazohusiana na utafiti huu ikiwa ni pamoja na upimaji “nerve conduction studies” utalipwa na wachunguzi.

### **JE, UTAPATA REJESHEWA KWA PESA YOYOTE ITAKAYOTUMIKA KWA SEHEMU YA UTAFITI HUU?**

Ikiwa utafiti hautafanywa siku hiyo hiyo, washiriki watapewa posho ili kuwezesha safari yao ya kurudi.

### **JE, KAMA UTAKUWA NA MASWALI BAADAYE?**

Ikiwa una maswali zaidi au wasiwasi juu ya kushiriki katika utafiti hili, tafadhali piga simu au tuma ujumbe wa maandishi kwa wafanyakazi wa kujifunza kwa idadi iliyotolewa chini ya ukurasa huu.

Kwa habari zaidi juu ya haki zako Kama mshiriki WA utafiti unaweza kuwasiliana Na Katibu / Mwenyekiti, Kenyatta National Hospital-Chuo Kikuu cha Nairobi, kamati ya Maadili na Utafiti kwa nambari: 2726300 Ext. 44102 barua pepe: uonknh\_erc@uonbi.ac.ke.

Watafiti watawalipa malipo yako kwa idadi hizi ikiwa wito ni kwa ajili ya mawasiliano inayohusiana na utafiti.

### **Je ni uchaguzi gani nyingine unaye?**

Uamuzi wako wa kushiriki katika utafiti ni wa hiari. Wewe ni huru kupinga kushiriki katika utafiti na unaweza kujiondoa kwenye utafiti wakati wowote bila udhalimu au kupoteza faida yoyote.

### **FORM YA KIBALI (TAARIFA YA IDHINI)**

#### **Taarifa ya Mshiriki**

Nimesoma fomu hii ya idhini au nilisomewa habari. Nimekuwa na fursa ya kujadili utafiti huu na mtafiti. Nimekuwa na maswali, akajibu kwa lugha ambayo ninayoelewa. Hatari na faida zimeelezwa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni hiari

nakwamba ninaweza kuchagua kujiondoa wakati wowote. Ninakubali kwa hiari kushiriki katika utafiti huu.

Ninaelewa kuwa jitihada zote zitafanywa ili kuweka habari kuhusu siri ya utambulisho wangu binafsi.

Kwa kutia saina fomu hii ya kibali, sijaacha haki yoyote ya kisheria ambayo mimi nishiriki katika utafiti.

Nakubali kushiriki katika utafiti huu : Ndiyo / Hapana

Nakubaliana kutoa maelezo ya mawasiliano kwa kufuatiliwa: Ndiyo / Hapana

**Jina la kuchapishwa la mshiriki:**

\_\_\_\_\_

saina ya mshiriki / Saina ya vidole \_\_\_\_\_ Tarehe \_\_\_\_\_

**Taarifa ya Mtafiti**

Mimi, aliyechaguliwa, nimemwelezea kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyechaguliwa hapo juu na kuamini kwamba mshiriki ameelewa na ametoa kibali chake kwa hiari.

**Jina la Mtafiti:** \_\_\_\_\_ **Tarehe:** \_\_\_\_\_

**Sahihi** \_\_\_\_\_

**Jukumu katika utafiti:** \_\_\_\_\_ (Mtafiti ambaye alielezea fomu ya kibali cha habari.)

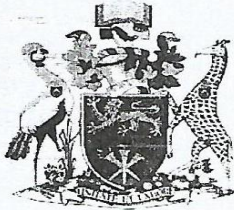
Kwa maelezo zaidi wasiliana na Dr Wendo C A Matilda, Tel: 0702490815 katika Chuo Kikuu cha Nairobi, idara ya dawa za kliniki na matibabu, kutoka 8:00 asubuhi hadi saa 5:00 jioni.

**Jina la Kuchapishwa kwa Shahidi (Ikiwa shahidi ni muhimu, shahidi ni mtu anayekubaliana na mtafiti na mshiriki)**

**Jina** \_\_\_\_\_ **Maelezo ya mawasiliano** \_\_\_\_\_

**Sahihi / kitambulisho:** \_\_\_\_\_ **Tarehe;** \_\_\_\_\_

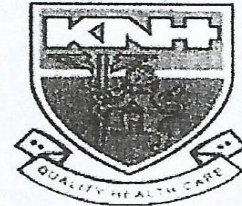
## 12.8 Appendix VIII : KNH-UON ERC APPROVAL



UNIVERSITY OF NAIROBI  
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P O BOX 19676 Code 00202  
Telegrams: varsity  
Tel: (254-020) 2726300 Ext 44355



KNH-UON ERC  
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Website: <http://www.erc.uonbi.ac.ke>  
Facebook: <https://www.facebook.com/uonknh.erc>  
Twitter: @UONKNH\_ERC [https://twitter.com/UONKNH\\_ERC](https://twitter.com/UONKNH_ERC)



KENYATTA NATIONAL HOSPITAL  
P O BOX 20723 Code 00202  
Tel: 726300-9  
Fax: 725272  
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/72

22<sup>nd</sup> February, 2018

Dr. Wendo Matilda Cynthia Auma  
Reg. No.H58/74639/2014  
Dept. of Clinical Medicine and Therapeutics  
School of Medicine  
College of Health Sciences  
University of Nairobi

Dear Dr. Wendo

**RESEARCH PROPOSAL – PREVALENCE AND ELECTROPHYSIOLOGICAL TYPES OF PERIPHERAL NEUROPATHY IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS AT KENYATTA NATIONAL HOSPITAL (P633/11/2017)**

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 22<sup>nd</sup> February 2018 – 21<sup>st</sup> February 2019.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Protect to discover

Yours sincerely,



**PROF. M. L. CHINDIA**  
**SECRETARY, KNH-UoN ERC**

- c.c.    The Principal, College of Health Sciences, UoN  
         The Deputy Director, CS, KNH  
         The Chairperson, KNH-UON ERC  
         The Assistant Director, Health Information, KNH  
         The Dean, School of Medicine, UoN  
         The Chair, Dept. of Clinical Medicine and Therapeutics, UoN  
         Supervisors: Prof. George Omondi Oyoo, Dr. T.O.O. Kwasa, Dr.M.C. Maritim