

**OUTCOME OF COMPRESSION THERAPY AS
AN ADJUNCT VERSUS STANDARD
TREATMENT IN THE MANAGEMENT OF LIMB
CELLULITIS AT KENYATTA NATIONAL
HOSPITAL**

This dissertation is submitted in part fulfillment for the award of Master of Medicine in
General Surgery degree of the University of Nairobi

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MAY, 2015

STUDENT'S DECLARATION

This dissertation is my original work and has not been published elsewhere or presented for a degree in any other university.

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H58/63713/2010

SUPERVISORS' DECLARATION

1. This dissertation has been submitted for examination with my approval as a university supervisor

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TABLE OF CONTENTS

STUDENT’S DECLARATION	ii
SUPERVISORS’ DECLARATION	iii
DECLARATION OF ORIGINALITY FORM.....	iv
ACKNOWLEDGEMENT	v
TABLE OF CONTENTS.....	vi
LIST OF FIGURES AND TABLES.....	viii
LIST OF ABBREVIATIONS.....	ix
ABSTRACT.....	x
1. INTRODUCTION	1
2. LITERATURE REVIEW	2
Aetiology	2
Risk factors	2
Clinical presentation	3
Classification of cellulitis	3
Investigations	3
Management of cellulitis.....	4
Venous ulcers and compression therapy.....	5
Lymphoedema and compression therapy.....	7
Indications for compression therapy	8
Contraindications of compression therapy:.....	8
Disadvantages of compression therapy:.....	8
3. STUDY JUSTIFICATION	9
3.1 NULL HYPOTHESIS	9
4. OBJECTIVES OF THE STUDY	9
4.1 Broad objective:	9
4.2 Specific objectives:	9
5. METHODOLOGY	10
5.5.2 SAMPLING PROCEDURE:	11
5.6 INCLUSION CRITERIA.....	11
5.7 EXCLUSION CRITERIA	11
5.8 MATERIALS AND METHOD	11
5.9 DATA COLLECTION	14
5.10 DATA MANAGEMENT AND ANALYSIS	14

5.11 DATA PRESENTATION.....	15
5.12 QUALITY ASSUARANCE IN RESEARCH ACTIVITIES	15
5.13 LIMITATION OF THE STUDY	16
5.14 DELIMITATION.....	16
5.15 ETHICAL CONSIDERATION	16
6. RESULTS	17
6.1. DEMOGRAPHIC CHARACTERISTICS	17
6.2. CLINICAL PRESENTATIONAND PAST MEDICAL HISTORY	18
6.3. ASSESSMENT OF PAIN, OEDEMA AND TENDERNESS	20
Pain evaluation on day 2 and day 3.....	20
6.4. EFFECT OF INTERVENTION ON WBC COUNT	24
6.5. COMPLICATIONS	24
7. DISCUSSION.....	25
8. CONCLUSIONS AND RECOMMENDATIONS	28
9. REFERENCES:	30
10. APPENDICES	33
APPENDIX 1	33
STUDY TIME FRAME.....	33
APPENDIX 2.....	34
BUDGET OF THE STUDY	34
APPENDIX 3.....	35
Data collection sheet/Questionnaire:	35
APPENDIX 4.....	37
CONSENT FORM:.....	37
APPENDIX 5: LETTER OF APPROVAL FROM ERC/KNH.....	47

LIST OF FIGURES AND TABLES

FIGURES

Figure 1: Illustrating enrollment, allocation, follow-up and analysis.	15
Figure 2: Sex of patients managed for cellulitis in KNH according to treatment group.....	17
Figure 3: Age of patients managed for cellulitis in KNH according to treatment group.....	18
Figure 4: Baseline pain presentation on day 1	20
Figure 5: Evaluation of pain on day 2 and day 3	21
Figure 6: Evaluation of oedema on day 2 and day 3.....	22
Figure 7: Tenderness in patients presenting with cellulitis and managed by compression therapy or standard treatment on day 1	23

TABLES

Table 1: Medical history of patients on management for limb cellulitis in KNH.....	19
Table 3: Evaluation of WBC count in patients with elevated WBC on days 2 and 3.....	24
Table 2: Evaluation of tenderness score in patients with cellulitis at KNH on days 2 and 3.....	24

LIST OF ABBREVIATIONS

ABPI – Ankle Brachial Pressure Index

ADL – Activities of daily living

Cm – Centimeter

CREST –Clinical Resource Efficiency Support Team for Health Service in Northern Ireland

CRP – C- reactive protein

Dkt –Daktari

Dr - Doctor

ERC - Ethics and Research Committee

ESR –Erythrocyte sedimentation rate

KNH - Kenyatta National Hospital

SD –Standard deviation

SOPC - Surgical Out-Patient Clinic

SPSS - Statistical Package for Social Sciences

TBC – Total blood count

UON - University of Nairobi

WBC – White blood cells

ABSTRACT

Background:

Cellulitis is a common condition causing significant morbidity. Treatment is mainly by use of antibiotics, limb elevation and analgesics.

Compression therapy is not used routinely in management of cellulitis but has been extensively used in treatment of lymphoedema and venous ulcers.

Objective:

To determine the outcome of use of compression therapy as an adjunct in the treatment of limb cellulitis compared to the use of standard treatment at Kenyatta National Hospital (KNH).

Study design: A randomized controlled trial.

Setting: Accident and Emergency department, outpatient clinics and the wards at KNH.

Patients and methods:

Patients aged 12 years and above with cellulitis were recruited into the study. Patients were randomly assigned to one group which was put on conventional treatment while in the other half compression therapy was added. Randomization was done using a table of random numbers.

Data was collected using questionnaires. Follow up for three days was done and thereafter weekly for two weeks.

Data was entered into an access database. Differences of the patients in the two categories were analyzed using T-test for continuous data and chi-squared test for categorical data using SPSS version 16.

Results:

The results were presented using tables and charts. Compression therapy was associated with greater reduction in pain compared to the conventional treatment. There was over 90% reduction for compression therapy group versus 65% in standard treatment group on day three. Tenderness resolved earlier on those on compression therapy and this was statistically significant. (95.7% in the compression group versus 82.5% in the standard treatment group)

Oedema was found to resolve better in those on compression therapy. However, this was not statistically significant. (P values of 0.16 and 0.136 for days 2 and 3 respectively)

Conclusion:

The use of compression therapy is more effective in control of pain and tenderness in patients with cellulitis of the limbs when compared to conventional treatment.

1. INTRODUCTION

Cellulitis is a non-necrotizing, non-suppurative inflammation of the skin and subcutaneous tissues usually from acute infection. It is a common condition which causes significant morbidity. There is need to find an effective treatment for the condition in a bid to reduce hospital stay and the cost of treatment^{1,2}.

Streptococcal species is the most common cause of diffuse cellulitis that is not associated with a defined portal of entry. Staphylococcus aureus is the usual causative organism in purulent cellulitis³.

The management of cellulitis mainly involves use of broad spectrum antibiotic such as flucloxacillin, which eradicates the causative organisms; analgesics which are used to treat the associated pain and inflammation whereas elevation of the affected limb helps in reducing the oedema and aids in venous return through the help of gravity. The antibiotic is given either intravenously or orally. Addition of metronidazole either orally or intravenously is done when diabetes or immune suppression is present. Non-steroidal anti-inflammatory drugs are the preferred analgesics. The limb is elevated when resting or sleeping. This is the conventional treatment for this condition. A wound, when present, is managed with an appropriate antiseptic and gauze dressing²⁵.

Addition of compression, therefore, is likely to result in faster resolution of the oedema by its action of forcing fluid from the interstitial spaces back into the vascular and lymphatic compartments. It also enhances oxygen and nutrients delivery at the cellular level. It may also improve bioavailability of antibiotics in the affected limb resulting in enhanced healing¹⁰.

Clinical Resource Efficiency Support Team (CREST) guidelines for wound management of 1998 recommended use of compression bandages in cellulitis once acute symptoms have improved³⁵. However; this has not been validated in our set up. This study compared the use of compression therapy as an adjunct with the conventional treatment of cellulitis at Kenyatta National Hospital (KNH).

2. LITERATURE REVIEW

Cellulitis is a spreading non-suppurative bacterial infection of the dermis and subcutaneous tissues characterized by erythema, swelling, warmth, and pain^{4,5}.

Aetiology

The etiologic agents are most often *Streptococcus pyogenes* and *Staphylococcus aureus*, followed by non- group A β -hemolytic streptococci and gram-negative bacilli. Recurrent streptococcal cellulitis of the lower extremities may be caused by organisms of group A, C, or G in association with chronic venous stasis or with saphenous venectomy for coronary artery bypass surgery. Less common organisms include *Strep. pneumoniae*, *Haemophilus influenzae*, gram-negative bacilli and anaerobes. Streptococci also cause recurrent cellulitis among patients with chronic lymphoedema resulting from elephantiasis, lymph node dissection, or Milroy's disease. Recurrent staphylococcal cutaneous infections are more common among individuals who have eosinophilia and elevated serum levels of IgE and among nasal carriers of staphylococci. Cellulitis caused by *Streptococcus agalactiae* (group B *Streptococcus*) occurs primarily in elderly patients and those with diabetes mellitus or peripheral vascular disease. *Haemophilus influenzae* typically causes peri-orbital cellulitis in children in association with sinusitis, otitis media, or epiglottitis. Tissue destruction and ulceration may follow, caused by release of streptokinase and other proteases. The infection can occur on anybody part; lower limbs are affected in most cases^{18,19}.

Risk factors

Risk factors for cellulitis of the lower limbs includes the presence of sites of entry for the aetiologic agent and predisposing factors, such as being overweight and having lymphoedema. Sites of entry are commonly created by traumatic injury, leg ulcers, and, possibly, dermatophytic toe web intertrigo^{20,21,23}.

A case control study in 1999 found that a potential site of entry (such as leg ulcer, toe web intertrigo, traumatic wound), lymphoedema, venous insufficiency and being overweight were all factors that could predispose to cellulitis.

Comorbidities such as diabetes and immune suppression increases susceptibility to and severity of cellulitis.

Clinical presentation

Cellulitis presents as an acute and progressive onset of a red, painful, hot, swollen and tender area of skin. The edge of the erythema may be well demarcated or more diffuse and typically spreads rapidly. Constitutional upset with fever and malaise occurs in most cases, and may be present before the localizing sign. Blistering, superficial haemorrhage into blisters,

Dermal necrosis, lymphangitis and lymphadenopathy may occur. The leg is the commonest site and there may be an identifiable portal of entry, such as a wound, an ulcer or signs of tinea infection. Bilateral leg cellulitis is very rare.

Complications include necrotizing fasciitis, myositis, subcutaneous abscesses, septicaemia, post-streptococcal nephritis and death²².

Deep venous thrombosis and thromboembolism may also complicate involvement in the lower limbs¹⁹.

Classification of cellulitis

The classification system serves as a useful guide for admission and treatment decisions. This classification was devised for skin and soft tissue infections²⁴.

Class I patients have no signs of systemic toxicity, have no uncontrolled co-morbidities and can usually be managed with oral antimicrobials on an outpatient basis.

Class II patients are either systemically ill or systemically well but with co-morbidity such as peripheral vascular disease, chronic venous insufficiency or morbid obesity which may complicate or delay resolution of the infection.

Class III patients may have a significant systemic upset such as acute confusion, tachycardia, tachypnoea, and hypotension or may have unstable co-morbidity that may interfere with a response to therapy or have a limb-threatening infection due to vascular compromise.

Class IV patients have sepsis syndrome or severe life threatening infection such as necrotizing fasciitis.

Investigations

Cellulitis is investigated using a Total Blood Count (TBC), Erythrocyte Sedimentation Rate (ESR) and C - reactive protein (CRP) which is a good marker of inflammation. It is used to monitor inflammation and infection. Although non-specific, nearly all patients have a raised white cell count, ESR or C-reactive protein. Normal results make a diagnosis of cellulitis less

likely. Total white cell count and differentials is evaluated using a total blood count. White cells protect against infection. Neutrophils, which are the most common type of white blood cells in the blood of adults, have a function in recognizing, ingesting and destroying foreign particles and microorganisms. Neutrophilia can result from infection, trauma and other inflammatory conditions.

Blood cultures can also be done. However, they should not be done routinely but should be reserved for Class III and Class IV cellulitis where they are more likely to yield the causative organism²⁴.

Moreover, cultures of any discharge from a wound can be done. However, even with needle aspiration of the leading edge or a punch biopsy of the tissue itself, cultures are positive in only 20% of cases. This observation suggests that relatively low numbers of bacteria cause cellulitis and that the expanding area of erythema within the skin may be a direct effect of extracellular toxins or the soluble mediators of inflammation elicited by the host^{17, 18}.

Doppler ultrasound of the limbs may be done to assess the vasculature and rule out deep venous thrombosis. Plain x-ray of the affected part may be done to rule out osteomyelitis which could complicate cellulitis.

Management of cellulitis

Class I patients are usually treated with oral antimicrobials and analgesics on an outpatient basis.

Class II patients are suitable for short-term (up to 48 hours) hospitalization and discharge on oral antimicrobial therapy.

Class III and IV patients require hospitalization until the infected area is clinically improving, systemic signs of infection are resolving and any co-morbidity is stabilized²⁴.

The drug of choice is penicillin, preferably broad-spectrum. Aggressive intravenous anti-Gram-positive antibiotics should be considered in severe infections. In diabetics and the immune-suppressed, appropriate Gram-negative and anaerobic cover should be included. Intravenous therapy is continued for seven days, followed by an appropriate oral therapy. Leg elevation is universally helpful and anticoagulation may be required⁴.

Surgical treatment in cellulitis entails management of complications. Wounds may need to be debrided or grafted. An abscess, when it forms, is drained. Early and adequate treatment has been shown to reduce the incidence of complications in this condition¹⁹.

Venous ulcers and compression therapy

An ulcer is the complete loss of epidermis and part of dermis. In the lower leg, it usually results from vascular disease with the vast majority (75%) due in part to venous hypertension. The main causes of leg ulceration include atherosclerosis, diabetes, sickle cell disease, tumors and trauma. A number of authors have listed oedema as a risk factor for ulceration in the lower limbs. Prompt treatment of oedema could help reduce this complication^{29,30}.

Many studies done on compression therapy are in venous ulcers treatment. Majority of venous ulcers can be induced to heal by application of adequate levels of sustained graduated compression. Compression therapy is, however, contraindicated in the treatment of ischemic ulcers. The majority of these studies have confirmed the benefit of compression therapy in venous ulcers treatment^{6,7}.

Peripheral arterial supply should be assessed in all patients by hand-held Doppler. Those individuals with an Ankle/Brachial Pressure Index (ABPI) less than 0.8 are likely to have arterial disease and therefore compression bandaging is contraindicated. Those with an ABPI greater than 0.8, graduated compression bandaging are essential for effective treatment. Therefore, this has to be determined in all patients with limb ulcers where compression therapy is being considered.

In absence of any evidence of compromised arterial supply, graduated compression bandages applied from toes to the knees enhance venous return and have been shown to be most beneficial in the healing of venous leg ulcers⁸.

In ulceration due to venous disease, oedema can be reduced by regular use of compression bandages; elevation of limbs and use of diuretics. Exudates and slough should be removed. Non-adherent dressings are usually used on such wounds. Surrounding venous eczema is managed with mild or moderately potent corticosteroids.

Antibiotic therapy is used only in overt infection. Vein surgery may help some younger patients with persistent venous ulcers.

The benefits of elastic compression stocking therapy for the treatment of chronic venous insufficiency and healing of ulcers have been well documented. In a retrospective review of 113 venous ulcer patients, the use of below-knee, 30- to 40-mm Hg elastic compression stockings, after first resolving oedema and cellulitis if present, resulted in 93% healing. Complete ulcer healing occurred in 99 of 102 (97%) patients who were compliant with stocking use versus 6 of 11 patients (55%) who were noncompliant ($p < 0.0001$). The mean time to ulcer healing was 5 months. Ulcer recurrence was less in patients who were compliant with their compression therapy. By life table analysis, ulcer recurrence was 29% at 5 years for compliant patients and 100% at 3 years for noncompliant patients. In more recent studies, the reported rate of venous ulcer healing with compression therapy is approximately 40 to 50% at 6 months¹⁶.

In addition to promoting ulcer healing, elastic compression therapy can also improve quality of life in patients with chronic venous insufficiency. In a recent prospective study, patients with chronic venous insufficiency documented by Doppler Ultrasound were administered a questionnaire to quantify the symptoms of swelling, pain, skin discoloration, cosmesis, activity tolerance, depression, and sleep alterations. Patients were treated with 30- to 40-mm Hg elastic compression stockings. There were overall improvements in symptom severity scores at 1 month after initiation of treatment. Further improvements were noted at 16 months post treatment³³.

Lymphoedema and compression therapy

Lymphoedema is an abnormal collection of protein-rich fluid in the interstitium resulting from obstruction of lymphatic drainage. Lymphatic obstruction causes an increase in the protein content of the extra-vascular tissue, with subsequent retention of water and swelling of the soft tissue. The increase in the extra-vascular protein stimulates proliferation of fibroblasts, organization of the fluid, and the development of a non-pitting swelling of the affected extremity²⁷.

Lymphoedema is caused by a compromised lymphatic system that impedes and diminishes lymphatic return. In primary lymphoedema, the failure is caused by congenital hypoplasia or aplasia of the peripheral lymphatics or by valvular incompetence. In secondary lymphoedema, the lymphatic drainage is altered by an acquired blockage of the lymph nodes or by disruption of the local lymphatic channels caused by etiologies such as recurrent attacks of lymphangitis a key type of which is cellulitis, malignancy, obesity and surgery^{35, 40}.

In addition to causing soft tissue swelling, lymphoedema opens channels in the integument and allows bacteria to enter the subcuticular space, which overwhelms host defenses and leads to cellulitis of the extremity. Patients with lymphoedema, therefore, are at increased risk of developing cellulitis in the affected extremity. Recurrent infection can damage the lymphatic vessels, aggravating the oedema^{15, 39}.

Graded compression stockings are widely used in the treatment of lymphoedema. The stockings reduce the amount of swelling in the involved extremity by preventing the accumulation of oedema while the extremity is dependent. When worn daily, compression stockings have been associated with long-term maintenance of reduced limb circumference. They may also protect the tissues against chronically elevated intrinsic pressures, which lead to thickening of the skin and subcutaneous tissue. Compression stockings also offer a degree of protection against external trauma³².

Elevation is an important aspect of controlling lower extremity swelling and is often the first recommended intervention. However, continuous elevation throughout the day can interfere with

quality of life more than lymphoedema itself. Elevation is an adjunct to lymphoedema therapy, but is not the mainstay of treatment³³.

There are two types of compression therapy; static and dynamic. Static compression has no graduated pressures and hence is not possible to determine the amount of pressure applied. Static compression involves use of such materials as a crepe bandage. Dynamic compression therapy may involve the use of multiple layered dressings innermost of which could be an absorptive dressing, then a padding followed by the compression bandage and finally an adhesive dressing to secure them. It involves graduated pressures. Graduated pressure is applied to the wound and the surrounding skin with greater pressures distally which gradually decreases proximally. Cellulitis can result from lymphatic obstruction and is usually associated with oedema. Therefore, compression therapy could be of value in the management of cellulitis.

Indications for compression therapy

The recognized indications for compression therapy includes, legs discomfort secondary to venous disease; lower limb oedema; skin changes due to venous insufficiency ; prevention and treatment of deep vein thrombosis; or superficial thrombophlebitis; venous leg ulcers and lymphoedema.

Contraindications of compression therapy:

Contraindication to the use of compression therapy includes, advanced peripheral obstructive arterial disease; severe uncontrolled congestive heart failure; septic phlebitis; advanced peripheral neuropathy.

Disadvantages of compression therapy:

Disadvantages of compression therapy includes discomfort and inconvenience to the patient; aesthetically unappealing; it may be expensive; the outcome can be catastrophic if used on arterial disease; determination of the right amount of pressure to use may be difficult; patient compliance is not easy to enforce.

3. STUDY JUSTIFICATION

Cellulitis is a common condition that manifests with inflammation resulting in limb oedema with subsequent ulceration if not well treated. Compression therapy has been used effectively in treating lymphoedema. Compression therapy could thus lead to reduced hospital stay and faster return to work. Since compression therapy has been shown to facilitate healing of chronic wounds and reduction of oedema, it could be useful in this case. Reduction of oedema decreases the incidence of complications such as ulceration. It also reduces pain and enhances healing.

Cellulitis causes significant morbidity. The outcome of this research could help in decreasing the cost of treatment as it may result in early cure. Moreover, the study has not been done before.

3.1 NULL HYPOTHESIS

There is no difference between the management of cellulitis with static compression therapy as an adjunct and using conventional treatment.

4. OBJECTIVES OF THE STUDY

4.1 Broad objective:

To study the outcome of static compression therapy as an adjunct to standard treatment compared to the use of standard treatment alone in the treatment of cellulitis of the limbs at Kenyatta National Hospital.

4.2 Specific objectives:

1. To determine the demographic data of the patients suffering from cellulitis.
2. To find out the time taken for at least 50% reduction in pain, oedema and tenderness using the two methods.
3. To compare the two methods as to the time taken for the white cell count to decrease by at least 50% from the elevated level if previously deranged.

5. METHODOLOGY

5.1 STUDY DESIGN: This was a randomized controlled trial. (RCT)

5.2 STUDY SETTING: Accident and Emergency department, wards, and outpatient clinics at Kenyatta National Hospital.

5.3 STUDY POPULATION: Patients presenting to Accident and Emergency department, clinics or admitted in the wards with cellulitis of the limbs classified as I or II at Kenyatta National Hospital.

5.4 STUDY DURATION: The study was conducted over six months period from October 2014 to March 2015.

5.5 SAMPLING:

5.5.1 SAMPLING FORMULA:

Formulae for sample size calculations for comparisons between proportions in a randomized control trial when the outcome is dichotomous:

$$n = \frac{2(Z_1 + Z_2)^2 \times \sigma^2}{(\mu_1 - \mu_2)^2}$$

n = is the sample size for each group = 40 (i.e. 80 patients in total for the 2 arms)

Z_1 = 1.96 representing 95% confidence interval

Z_2 = 0.84 for a power of 80%

μ_1 = Average duration (in days) for healing in the group receiving standard management assumed to be 7 days

μ_2 = Average duration (in days) for healing in the group receiving compression management assumed to be 6.5 days

σ^2 = SD for average duration to healing assumed to be 0.8

$$n = \frac{2(1.96 + 0.84)^2 \times 0.8^2}{(7 - 6.5)^2}$$

$n = 40.1408$

$2n = 80$

5.5.2 SAMPLING PROCEDURE:

Consenting patients who met inclusion criteria were enrolled cumulatively by the principal researcher or research assistant until the required sample size was obtained.

5.6 INCLUSION CRITERIA

All patients aged 12 years and above, diagnosed with cellulitis of the limbs classified as I and II at casualty, outpatient clinics and in the wards and who consented to participate in the study were included.

5.7 EXCLUSION CRITERIA

- All those who declined to sign consent.
- Presence of an abscess or septic arthritis.
- Patients with class III or IV cellulitis.
- Advanced peripheral obstructive arterial disease.
- Severe uncontrolled congestive heart failure.
- Septic phlebitis.
- Advanced peripheral neuropathy.

5.8 MATERIALS AND METHOD

Informed consent, which included possible complications and disadvantages of compression therapy, was obtained from all patients recruited into the study before treatment was started. Consent for those below eighteen years was signed by a relative or guardian. Assent was also obtained for those below eighteen years.

Patients, twelve years of age and above, with cellulitis of the limbs classified as I or II, were randomly assigned to either of the treatment methods and followed over three days and thereafter weekly for two weeks. The patients were reviewed by the principal researcher or his assistants. This included complete history and physical examination in order to make a diagnosis and categorize the patients into various categories. Only those in class I or II were recruited into the study. Those who did not meet the inclusion criteria or refused to participate were excluded. Those selected were then randomized and allocated to either of the treatment groups. Risk factors and complications present were recorded. The computer was used to generate numbers and each number was then used to assign patients either to the standard treatment group or

compression therapy group. Patients were recruited from the wards, Accident and Emergency department and outpatient clinics. There was no blinding in the study.

Patients in the wards were allocated the intervention group at the time of admission at the casualty or outpatient clinic or at the first contact for those already in the ward during the study.

The recruitment was done by the principal researcher or his assistant using random numbers to determine the intervention for each patient. The research assistants were selected from a qualified and registered medical officer intern and clinical officer intern who were specifically trained by the principal researcher before the start of the research. There were two research assistants consisting of two clinical officer interns. The training focused on diagnosis and treatment of cellulitis including the technique of application of the compression bandage and consent taking.

Crepe bandage application technique:²⁴

1. Each turn of the bandage was of equal tension.
2. Bandage was applied in a spiral form overlapping the preceding layer by 50%.
3. Sizes of crepe bandages used: adults – large; children (12-17years) depended on their body size and weight – either medium or large.

Patients with class I cellulitis were put on oral antibiotics whereas those with class II cellulitis were started on intravenous antibiotics for 48 hours then changed to appropriate oral antimicrobial. Analgesics were given as necessary. The patients randomized to the compression therapy group had compression bandage applied on the affected limbs in addition to the above.

Follow up for two days was done mainly in the wards and outpatient clinics. Those in the wards were reviewed daily. All signs and symptoms were recorded in the patient file and in the researcher administered questionnaire at the first contact and during subsequent follow up. Any complication of cellulitis such as wounds, osteomyelitis and gangrene were noted and recorded.

Patients were advised to call the principal researcher or his assistants, whose phone contacts were provided, any time they had a problem or needed clarification.

A total blood count was done at the initial contact with the patient and on subsequent follow up for 2 days. One milliliter of blood was drawn on any one study occasion. This was mainly for the purposes of monitoring the white blood cell count which is an important sign of infection. This investigation was done on all patients recruited into the study. The same laboratory was used for a particular patient to monitor the total white cell count and the differentials.

During follow up, wounds, when present, were examined for signs of inflammation and healing. The wounds were then cleaned with saline or an appropriate antiseptic solution and dressed with sterile gauzes unless they were already healed. This was done by the principal researcher or his assistant. Crepe bandage was then applied if the patient was randomized into the compression therapy group.

The circumference of the affected limb was measured in centimeters and recorded. They were measured using a tape measure at their midpoints. For the upper limbs, mid-palm, mid-forearm and mid-arm were used whereas for the lower limbs, mid-foot, mid-leg and mid-thigh were used as the points for measuring. Comparisons with the normal limbs were done. This was done at the initial contact with the patient and in all subsequent reviews.

Pain was monitored with a pain score which involved patients self reporting of pain. It is used for adults and children ten years old and above³⁶. (Appendix 1)

Tenderness was monitored using a tenderness scale. The scale grades tenderness from 1-4 with grade 1 only complaining of pain on palpation and grade 4 with patient not allowing palpation³⁷. (Appendix 1)

The principal researcher or his assistant applied the crepe bandage at the initial contact with the patient and during subsequent visits. The bandage remained in place until the next review. The patient was also advised to elevate the involved limb when sitting or lying down.

Follow up reviews was done on days two and three. There were at least three contacts with the patient during the research. At first contact with the patient; on the second day and on the third day.

The patients were required to report any adverse events to the principal researcher who will then forward it to the Ethics Committee for appropriate action.

5.9 DATA COLLECTION

Interviewer administered predesigned questionnaires were used at first contact with the patients and subsequently by the principal researcher and his assistants.

Patients were reviewed either in the casualty or wards and followed up on days two and three. Questionnaires were filled in all the reviews.

5.10 DATA MANAGEMENT AND ANALYSIS

All the findings were used strictly for the purposes of research and patients' details were held in confidence. Data was entered using Microsoft Excel and analyzed using SPSS version 16. Each questionnaire had a serial number, age, and gender and unit number of the patient. The data was cleaned, validated and stored in a password protected folder.

Analysis was done on an intention-to-treat basis for all participants.

Descriptive univariate analysis of socio-demographic characteristics (such as age and gender) was analyzed and presented using percentages, frequency tables and graphs. Continuous variables included pulse, oedema and time taken for healing to occur and white blood cell count. Categorical variables included sex, pain, and history of trauma, co-morbidities, medications, tenderness and complications. During analysis, the rating scale was converted into a categorical variable with four levels: no pain; mild pain; moderate pain and severe pain.

Primary outcome was the mean healing duration in days in the two groups. Inferential analysis was conducted using the two samples T-test to compare mean duration for the standard versus compression group.

For the secondary objectives measuring mean reduction in pain, oedema, tenderness and white cell count normalization, T-test was used to compare averages in the two groups.

A p-value less than 0.05 was considered significant.

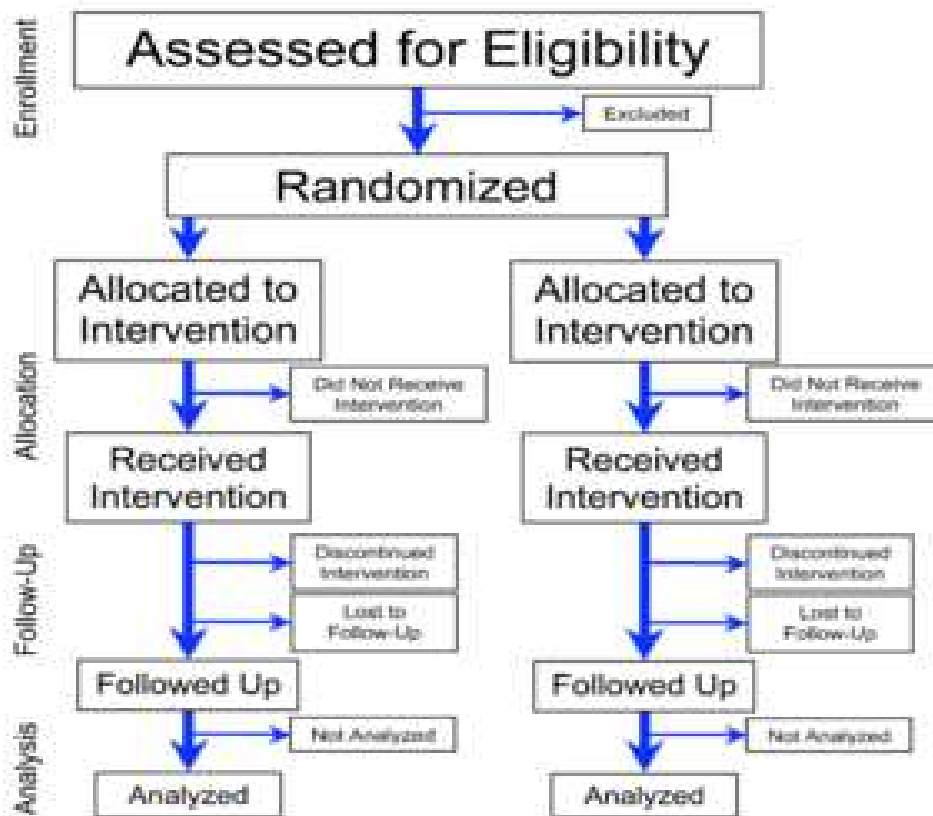


Figure 1: Illustrating enrollment, allocation, follow-up and analysis.

5.11 DATA PRESENTATION

The outcome of the analysis was presented using tables and graphs.

5.12 QUALITY ASSUARANCE IN RESEARCH ACTIVITIES

Principal researcher trained the research assistants in the diagnosis of cellulitis. The assistants were also trained on proper application of the compression dressing.

Consent for all patients was obtained by the principal researcher. In addition, allocation to the treatment groups was done by the principal researcher.

The same drugs were used for all patients for the same duration. Intravenous drugs were given for forty eight hours when necessary. Oral medications were given for one week.

Follow-up for two days was done for all patients.

The same laboratory was used for each patient to ensure the accuracy of the results. Kenyatta National Hospital laboratories were used for all patients.

5.13 LIMITATION OF THE STUDY

1. Pain perception from patients could be subjective. For instance perception of pain by various individuals may be affected by one's culture and gender.
2. Follow up for patients after discharge or as outpatients was difficult.

5.14 DELIMITATION

Over 90% of the patients in the study were in-patients hence it was easy to make follow up.

5.15 ETHICAL CONSIDERATION

Approval to carry out the research was sought from the University of Nairobi and KNH Ethics and Research Committee. The study was started after approval from the ethics committee. All patients recruited to the study were required to sign an informed consent by the principal researcher. Those who declined to give consent were treated in the normal way. The data obtained from the study was kept confidentially.

6. RESULTS

6.1. DEMOGRAPHIC CHARACTERISTICS

Figure 2 and figure 3 shows that the treatment groups were not significantly different in terms of gender ($p = 0.485$) and age ($p = 0.452$) distribution. Approximately two-thirds (67.5%) of patients on compression therapy were males compared to 60% of those on standard treatment. (Figure 2)

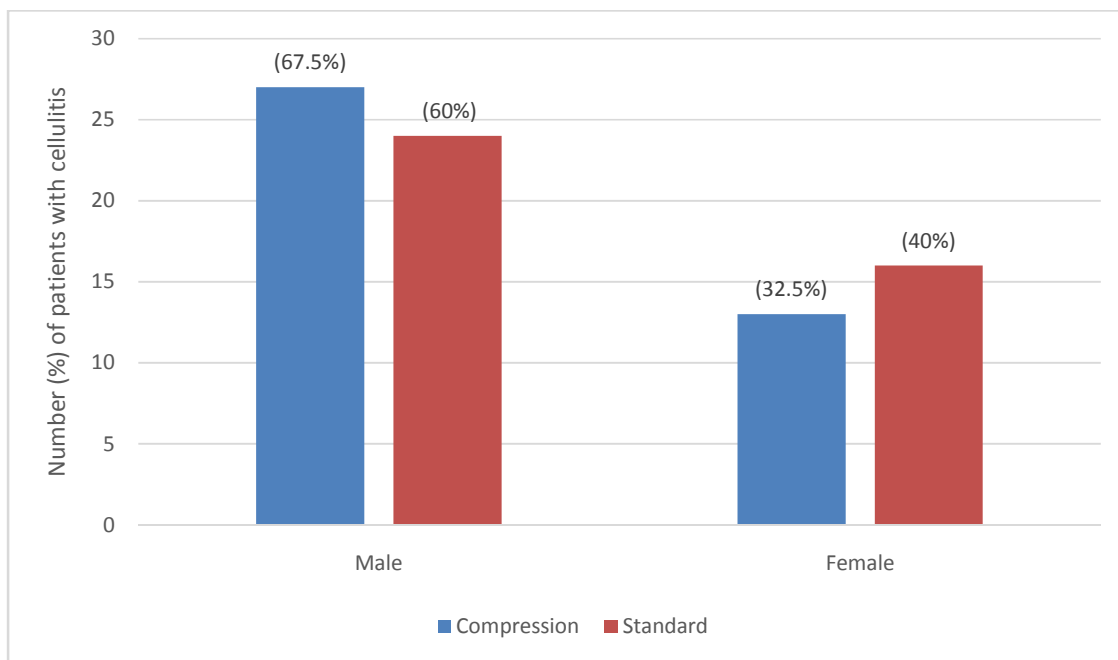


Figure 2: Sex of patients managed for cellulitis in KNH according to treatment group

The mean age of patients in the compression therapy group was 39.8 years ($SD = 17$) compared to a mean age of 37.7 years ($SD = 16$) in the standard treatment group.

Figure 3 shows that the modal age group in the compression therapy group was 30-39 years and 50 years and above (11, 27.5%) compared to the standard treatment group which was 20-29 years (14, 35%).

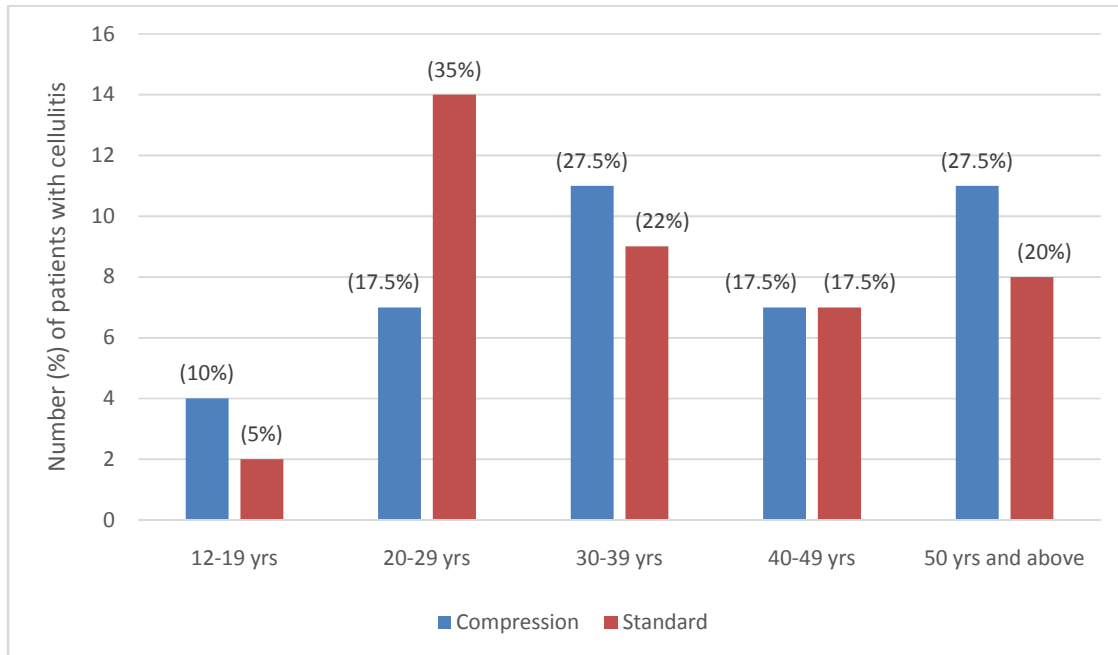


Figure 3: Age of patients managed for cellulitis in KNH according to treatment group

6.2. CLINICAL PRESENTATION AND PAST MEDICAL HISTORY

Table 1 shows that there were no significant differences in the clinical presentation and past medical history of patients in the two treatment groups namely, compression therapy or standard treatment. History of trauma was reported in 62.5% and 67.5% of patients on compression and standard treatment, respectively ($p = 0.972$). Comorbid illnesses occurred in 20% and 25% of patients on compression therapy and standard treatment respectively ($p = 0.589$). Most patients in both compression therapy (72.5%) and standard treatment (95%) groups were currently on medications ($p = 0.792$) and 5% of patients in each group had previously been treated for cellulitis ($p = 0.931$).

Table 1: Medical history of patients on management for limb cellulitis in KNH

	Cellulitis management		P value
	Compression	Standard	
History of trauma			
Yes	25(62.5)	27(67.5)	0.972
No	10(25.0)	11(27.5)	
Any co-morbid condition			
Yes	8(20.0)	10(25.0)	0.589
No	30(75.0)	28(70.0)	
Any current medications			
Yes	29(72.5)	38(95.0)	0.792
No	2(5.0)	2(5.0)	
Any previous treatment for cellulitis			
Yes	2(5.0)	2(5.0)	0.931
No	32(80.0)	35(87.5)	

6.3. ASSESSMENT OF PAIN, OEDEMA AND TENDERNESS

Figure 4 shows that most patients had moderate pain on presentation (compression therapy 82.5% and standard treatment 62.5%) and the severity of pain was not significantly associated with the type of management that patients received (chi = 5.6, DF = 2; p = 0.06).

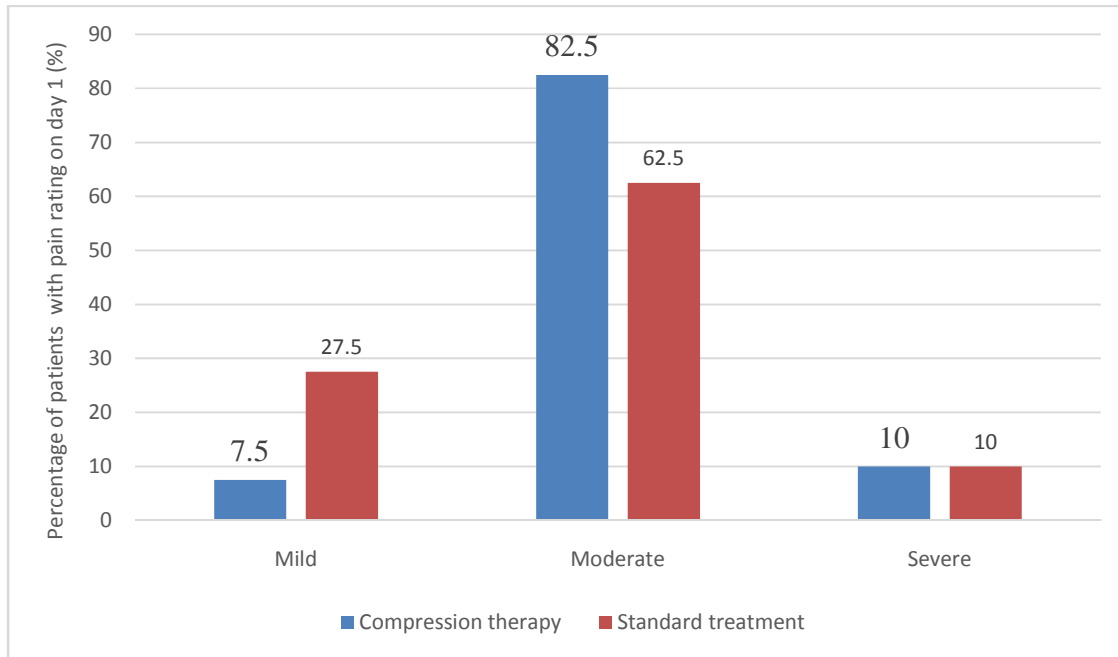


Figure 4: Baseline pain presentation on day 1

Pain evaluation on day 2 and day 3

As shown in Figure 5, there was a significant association between cellulitis management and the primary outcome of 50% reduction in the pain score on day 2 (p = 0.015) and day 3 (p = 0.003) upon evaluation. Compression therapy was associated with greater reductions in pain compared to standard management on both day 2 and day 3.

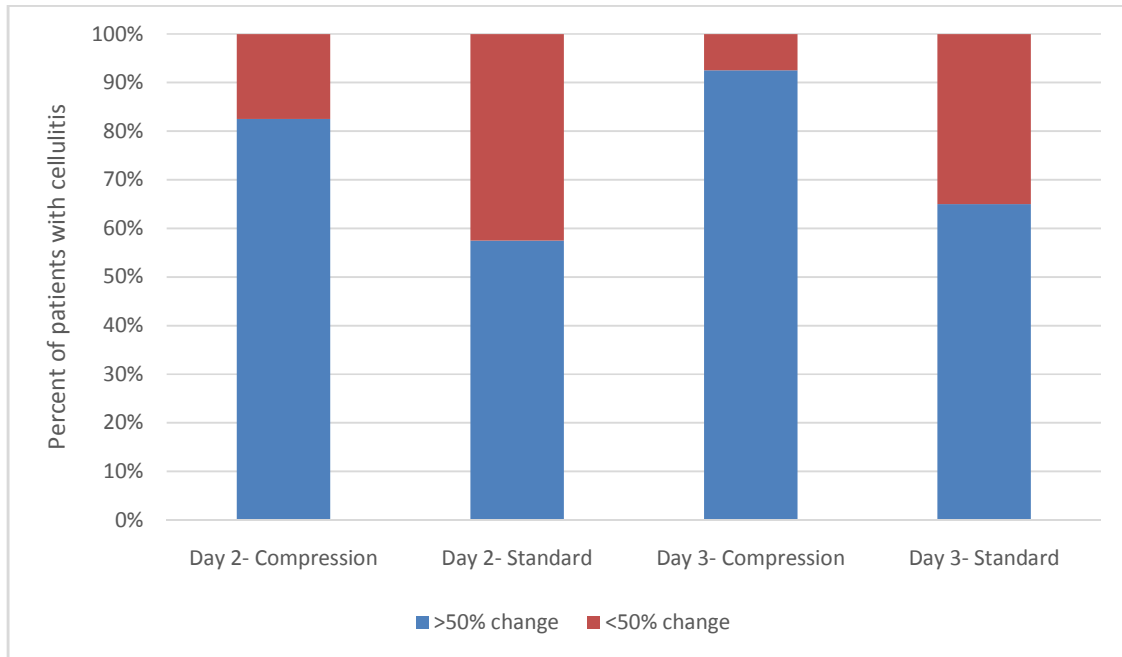


Figure 5: Evaluation of pain on day 2 and day 3

Oedema

Figure 6 shows that the duration taken for oedema to recede in patients with cellulitis was not significantly associated with the type of management that patients received on day 2 ($p = 0.16$) or day 3 ($p = 0.136$).

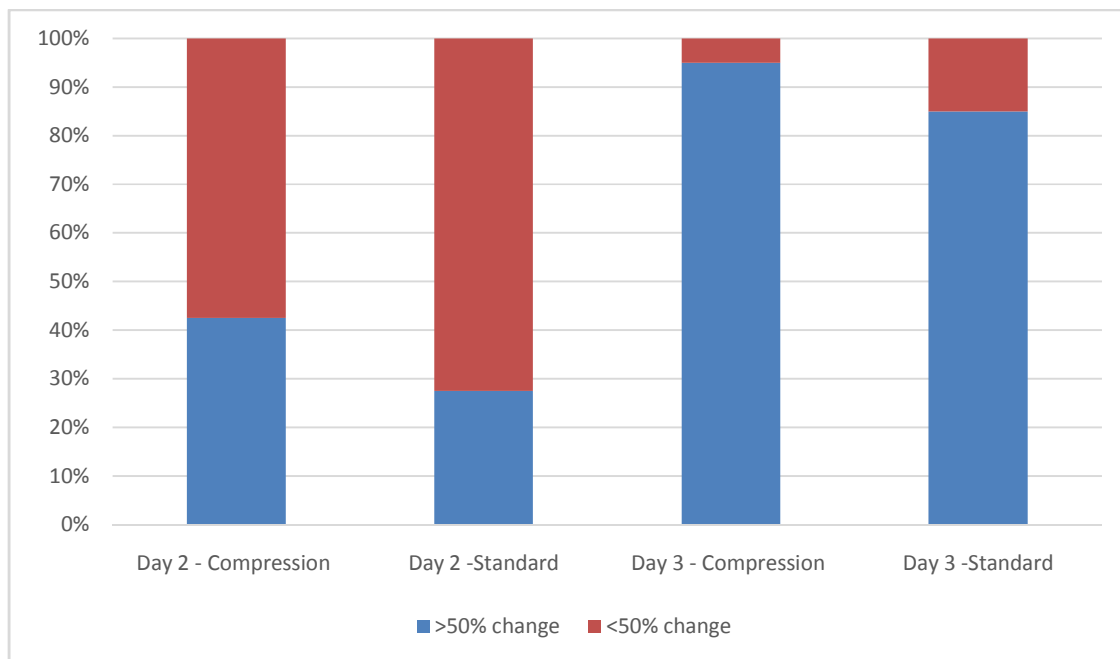


Figure 6: Evaluation of oedema on day 2 and day 3

Tenderness

Figure 7 shows that most patients with cellulitis managed using standard (67.5%) or compression (60%) therapy presented with tenderness manifesting as patients complaining of pain and wincing on palpation. The severity of tenderness related to cellulitis on presentation for care was not significantly associated with the management that patients eventually received.

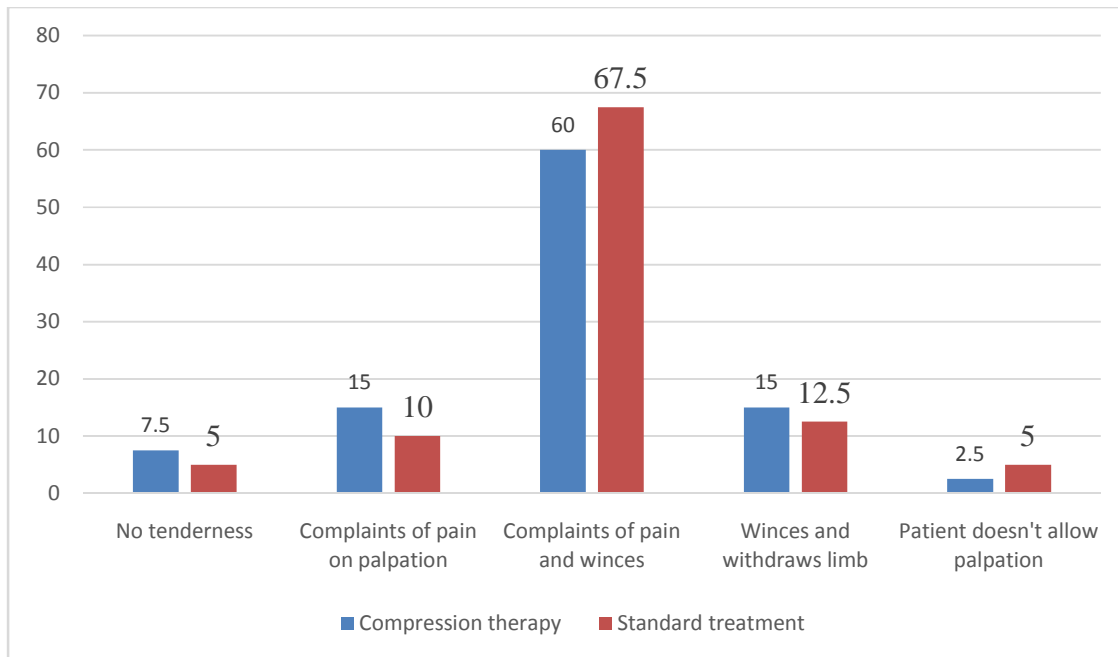


Figure 7: Tenderness in patients presenting with cellulitis and managed by compression therapy or standard treatment on day 1

Evaluation of tenderness on day 2 and day 3

Table 2 shows that during evaluation on day 2, 95% of patients on compression therapy had had 50% reduction in scores compared to 75% of patient on standard treatment ($p = 0.012$). On day 3, those experiencing 50% reduction in tenderness scores were 97.5% in compression therapy group compared to 82.5% in standard treatment group ($p = 0.025$).

Table 2: Evaluation of tenderness score in patients with cellulitis at KNH on days 2 and 3

	Cellulitis management		Chi square	P value
	Compression	Standard		
Tenderness assessment on day 2				
>50% change	38(95.0)	30(75.0)	6.3	0.012
<50% change	2(5.0)	10(25.0)		
Tenderness assessment on day 3				
>50% change	39(97.5)	33(82.5)	5.0	0.025
<50% change	1(2.5)	7(17.5)		

6.4. EFFECT OF INTERVENTION ON WBC COUNT

Table 3 shows that the WBC count was elevated in 24 patients in the compression therapy group and 22 patients in the standard treatment group. Elevated WBC counts reduced by 50% in 95.8% and 100% of patients on compression and standard treatment by day 2 respectively, and on day 3 all the patients with elevated WBC counts had reductions of 50% or more compared to admission WBC counts.

Table 3: Evaluation of WBC count in patients with elevated WBC on days 2 and 3

	Cellulitis management	
	Compression (n = 24)	Standard (n = 22)
WBC assessment on day 2		
>50% change	23(95.8)	22(100.0)
<50% change	1(4.2)	0(0.0)
WBC assessment on day 3		
>50% change	24(100.0)	22(100.0)

6.5. COMPLICATIONS

14 patients (17.5%) had complications which were minor. These included abscesses, wounds, blisters and osteomyelitis.

7. DISCUSSION

Static compression therapy was used in this study since it was readily available and affordable compared to dynamic compression. The majority of patients treated at KNH is mainly of the low economic status and hence cannot afford expensive treatment modalities.

Most of the patients with cellulitis were male (64%). 74 patients were aged 20 years and above. Cellulitis was less common in the younger population. This could be resulting from a better immunity of the younger population.

Older patients were also more prone to physical trauma owing to their greater mobility in their daily activities since they would be involved in providing for their families. In most patients, trauma was the major predisposing factor reported. All the studies done on cellulitis noted trauma as one of the main predisposing factor. Bjorsdottir *et al* in a study on lower limb cellulitis in 2005 found trauma to be a major riskfactor²¹. This is consistent with other studies done on risk factors for cellulitis. In this study, history of trauma was reported in 60% of those recruited. This highlights trauma as one of the major cause of limb cellulitis. Men tend to be involved in risky occupations and this could explain the greater prevalence in this gender. Lower limbs formed the bulk of affected extremities probably due to their exposed position.

A study done in 1999 by Margolis *et al* found the lower limb as the most affected area by cellulitis with causes including leg ulcer, toe web intertrigo, trauma and lymphoedema³⁴.

Forty five per cent of the patients had co-morbidities. Comorbid conditions were prevalent in those aged above 50 years. The conditions reported included diabetes and HIV infection. Much co-morbidity has been associated with cellulitis as a predisposing factor. Some, such as diabetes, are known to result in severe disease with more complications. Many studies have associated the elderly with increased co-morbidities. This study also found co-morbidities such as diabetes and hypertension to be increased among those aged fifty years and above. However, HIV infection was more common in younger patients. This could be due to the younger patients being more sexually active compared to the elderly.

On average, 83% of the patients were on treatment either for the co-morbid condition or for current symptoms with most being on antibiotics and analgesics.

Only 5% of the respondents had been treated previously for cellulitis of the limbs. The disease is probably under-diagnosed in the community. Treatment is also delayed in most patients.

Ninety eight per cent of the study subjects were in-patients. Evaluation and follow up was mainly in the ward. A few were evaluated in casualty and none in the outpatient clinics. This made follow-up easy with no loss to follow-up. The investigations were done in the ward daily for three days. Most patients were discharged after a week on oral medications.

Most patients had moderate pain on presentation which significantly reduced when the interventions were instituted. However, compression therapy was associated with greater reduction in pain compared to standard treatment on both days of follow up. Cellulitis management usually involves use of antibiotics and analgesics. In addition, patients are encouraged to rest the limb and elevate it. Addition of compression dressing to the treatment could have possibly reinforced the resting of the limb hence the improvement in pain on the second and third day. Studies have established cellulitis as a skin and subcutaneous infection and responds well to antimicrobials. A prospective study done by Perl et al of non-purulent cellulitis among 179 hospitalized patients found that beta-hemolytic streptococci accounted for 73% of cases. Despite the lack of an identifiable etiology in 27 % of cases, the overall clinical response rate to beta-lactam therapy was 96 %^{18,38}.

Reduction in oedema was not significantly different in the two groups. However, oedema was noted to decrease more in the compression therapy group although not statistically significant.

Compression dressing has been used extensively in lymphoedema and venous ulcers with faster resolution of the oedema. Oedema in cellulitis results from inflammation whereas in lymphoedema it results from collection of protein-rich fluid in the interstitium from obstruction of lymphatic drainage. The use of antibiotics and anti-inflammatory medications will eliminate the causative organisms and decrease the inflammation. This could explain the resolution of symptoms equally in the two groups. The reduction was not dependant entirely on the compression. Elevation facilitates gravity drainage of oedema and inflammatory substances. Many patients with cellulitis have underlying conditions that predispose them to developing recurrent cellulitis including tinea pedis, lymphoedema, and chronic venous insufficiency. In such patients, treatment should be directed at both the cellulitis and the predisposing condition.

Patients with oedema may benefit from treatment with compressive stockings and diuretic therapy. The approach to antibiotic selection for treatment of cellulitis depends on whether the clinical presentation consists of purulent or non-purulent cellulitis. The duration of therapy should be individualized depending on clinical response. Five to ten days is usually appropriate. Longer duration of therapy may be warranted in patients with severe disease.⁴⁵

Over 60 per cent of patients on palpation of the limbs complained of pain and winced. This was graded as 2. Tenderness reduced more in the compression therapy group compared to the standard treatment. Adding a compression to the affected limb probably resulted in better compliance by the patients in resting and elevating the affected limb. This would be different in the standard treatment in which the patients did not comply as well. This could probably be the reason for better response in the compression group. Compression dressing probably facilitates venous return and enhances oxygen and nutrients delivery at the cellular level. This could lead to improved bioavailability of the drugs in the affected limb enhancing healing.⁵

Most of the complications found on the patients included wounds which affected nine patients. Two patients had abscesses on the affected limbs; two had blisters while one patient had osteomyelitis. However, these complications did not affect the management of these patients. Cellulitis can be a complication of conditions such as lymphoedema. However, complications of cellulitis are not common. There are few studies that examine specifically the incidence of complications in cellulitis.

On systemic examination, two patients had associated fractures on the affected limbs. These, however, did not alter the management or outcome of these patients. Injuries associated with this condition are always treated to facilitate its resolution.

Forty six patients (57.5%) had leucocytosis on presentation which had normalized by the third day. There was no significant difference in the two groups. Studies done on cellulitis did not indicate raised white cell count as a major characteristic of the disease. Only 20% of blood cultures were positive in the majority of these studies.

8. CONCLUSIONS AND RECOMMENDATIONS

8.1 CONCLUSIONS

1. Use of compression therapy as an adjunct reduces pain more than standard treatment.
2. Addition of compression therapy to the conventional treatment of cellulitis decreases tenderness better.
3. There was an earlier resolution of the oedema with use of compression when compared to standard treatment. This, however, was not statistically significant.
4. Trauma is a significant cause of cellulitis of the limbs.
5. White cell count is not a good measure of inflammatory response in cellulitis.
6. Comorbid conditions were major risk factors for cellulitis in this study.
7. Use of compression therapy is not associated with any complication directly related to the intervention hence it is a relatively safe intervention.

8.2 RECOMMENDATIONS

1. Addition of compression therapy to the conventional treatment of cellulitis decreases tenderness better. Therefore, compression therapy is recommended in the management of cellulitis in this regard.
2. Compression therapy as an adjunct would be recommended in the management of cellulitis as it was found to lead to better reduction in tenderness.
3. The use of compression therapy solely to decrease oedema in cellulitis is not supported by the findings of this study.
4. Measures to reduce trauma, which could include government policy to reduce road traffic accidents, will go a long way in decreasing the burden of this disease.
5. A similar research should be carried out with C - reactive protein as the main laboratory investigation since it is a better measure of inflammatory response.

6. Comorbid conditions should be treated promptly and adequately to reduce the incidence of cellulitis since a significant number of patients had co-morbidities.

7. A study with a larger sample will need to be done to have sufficient evidence for the safety of use of compression therapy in treatment of cellulitis.

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10. APPENDICES

APPENDIX 1

STUDY TIME FRAME

ACTIVITY	APR 2014	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN 2015	FEB	MAR 2015
Proposal Development	■	■										
Proposal Presentation			■									
Ethical approval			■	■								
Data collection					■	■	■	■	■	■		
Data analysis and presentation of dissertation											■	■

APPENDIX 2

BUDGET OF THE STUDY

BUDGET ITEM	AMOUNT(KSH)
Research fee for UON/ KNH-ERC	2000
Statistician consultation	20000
Stationery, printing and binding	10000
Dressing materials(includes crepe bandages)	60000
Follow up	10000
Research assistants fees – 2 @ KSH 10000	20000
Contingency fee	10000
Total	132000

APPENDIX 3

Data collection sheet/Questionnaire:

Data collector:

(a) Demographic data:

Study number.....

In-patient number.....

Age (years).....

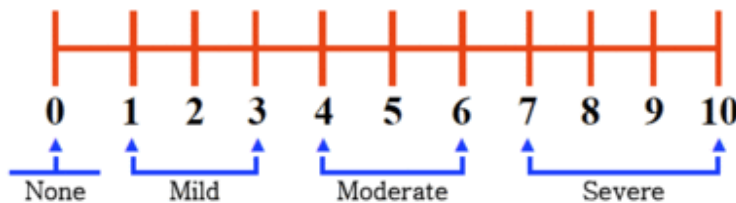
Gender/Sex.....

Residence.....

(b) History:

- i. Pain- NO PAIN: 0 MILD PAIN: 1-3 MODERATE PAIN: 4-6
SEVERE PAIN: 7-10

NUMERIC RATING SCALE FOR PAIN (NRS-11) – FOR ADULTS AND CHILDREN 10 YEARS AND ABOVE



RATING	PAIN LEVEL
0	No pain
1-3	Mild pain(nagging, annoying, little interference with ADL)
4-6	Moderate pain(interferes significantly with ADL)
7-10	Severe pain(disabling; unable to perform ADL)

- ii. History of trauma: YES NO
- iii. Any comorbid condition: YES NO
If yes, specify.....

iv. Any current medications: YES NO If yes, specify.....

v. Any previous treatment for the same symptoms: YES NO

(c) Physical examination:

i. Vital signs: Body temperature.....Pulse.....

ii. Local examination: limbs:

- Edema (circumference of the limb in cm): Affected..... Normal.....
- Tenderness

TENDERNESS SCALE/GRADING

GRADE	DESCRIPTION	SCORE –TICK
1	Complaints of pain on palpation	
2	Complaints of pain and winces	
3	Winces and withdraws limb	
4	Patient won't allow palpation	

- Any complications: PRESENT ABSENT

If present, specify.....

iii Systemic examination: Any other significant finding: YES NO

If yes, specify.....

(d) Investigations: Total TBC.....

Neutrophils.....

APPENDIX 4

CONSENT FORM:

English version;

This informed consent form is for patients of 12 years and above at the Kenyatta National Hospital diagnosed with cellulitis during the study period. We are requesting these patients to participate in this research project whose title is **“Outcome of compression therapy as an adjunct versus standard treatment in the management of limb cellulitis in Kenyatta National Hospital.”**

Principal investigator: Dr Kipsang, Joseph Kibet.

Institution: School of Medicine, Department of Surgery- University of Nairobi.

Supervisors: Prof. Khainga, S.O. and DrNangole F.W.

This informed consent has four parts:

1. Information sheet (to share information about the research with you).
2. Certificate of Consent (for signatures if you agree to take part).
3. Assent form for those below 18 years.
4. Statement by the researcher.

You will be given a copy of the full Informed Consent Form.

Part I: Information sheet:

My name is Dr. Kipsang, Joseph Kibet, a post-graduate student at the University of Nairobi’s School of Medicine. I am carrying out a study to determine, “The outcome of compression therapy as an adjunct versus standard treatment in the management of limb cellulitis at Kenyatta National Hospital.”

Cellulitis is a common disease caused by certain bacteria which invade the skin and subcutaneous tissue. It is normally treated with antibiotics and analgesics. Gauzes are usually used to dress any wound that may be present. The use of compression therapy in addition to antibiotics is likely to improve outcome of treatment in the management of this disease. However, this treatment modality has not been used locally. This study aims to determine the

outcome of the use of compression therapy in the management of limb cellulitis compared to the standard treatment in our set up after which recommendations to its efficacy will be made.

Some of the disadvantages of compression therapy include:

- It can cause some inconvenience and discomfort to you.
- It may not be aesthetically appealing.
- The outcome can be catastrophic if used on arterial disease.

To mitigate on the above disadvantages, thorough clinical examination and investigations will be done to rule out arterial disease before the application of the compression. Palpation of peripheral arteries will be done or a Doppler ultrasound used to locate the vessels to rule out arterial disease. Leg and arm blood pressures will be done and compared through a specific calculation for detection of arterial insufficiency. This will ensure that compression is not used on arterial disease. You are also advised to call the principal researcher or his assistant any time you have a problem. Their phone contacts will be provided to you. You are also required to contact the principal researcher any time there is a side effect of the treatment. The principal researcher will then report it to the Ethics Committee. Any adverse effect from the intervention will be treated appropriately.

I am inviting you to participate in this study and you are free to either agree immediately after receiving this information or later after thinking about it. You will be given the opportunity to ask questions before you decide and you may talk to anyone you are comfortable with about the research before making a decision. After receiving this information concerning the study, please seek for clarification from either myself or my assistant if there are words or details which you do not understand.

If you agree to participate, you will be asked to provide personal information and other details related to your disease. History of the present illness will be taken either by me or my assistants. You will also be examined from head to toe including measuring the affected limb. Blood samples shall be collected on the first day of being reviewed and thereafter daily for two days and analyzed in the laboratories using standard protocol. The test will be a complete blood count which assesses your blood picture. This will facilitate treatment of the disease.

All the information which you provide will be kept confidential and no one but the researchers will see it. The information about you will be identified by a number and only the researchers can relate the number to you as a person. Your information will not be shared with anyone else unless authorized by the University of Nairobi /Kenyatta National Hospital - Ethics and Research Committee (UON/KNH-ERC).

Your involvement in this research will be through an interview and clinical evaluation and interventional modality. Apart from the disadvantages mentioned earlier there are no other risks expected when you consent to participate. Your participation is voluntary and refusal to participate in the research or withdrawal from it will not affect the treatment which you receive at this hospital. All the information that you give us will be used for this research only.

All patients treated at the Accident and Emergency, outpatient clinics and the wards during the study period are invited to participate.

This proposal has been reviewed and approved by the UON/KNH-ERC which is a committee whose work is to make sure research participants like you are protected from harm. It was submitted to them through the Chairman, Department of Surgery, School of Medicine at the University of Nairobi with the approval of university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason.

- Secretary, UON/KNH-ERC,
P.O. Box 20723- 00202,
KNH, Nairobi.
Tel: 020-726300-9
Email: KNHplan@Ken.Healthnet.org

- Chairman,
Department of Surgery, School of Medicine - University of Nairobi,
P.O. Box 19676-00202,
KNH, Nairobi.
Tel: 020-2726300

- University of Nairobi research supervisors:

Prof. Khainga S.O.,

Department of Surgery, School of Medicine - University of Nairobi,

Tel: 020-2726300

Dr. Nangole, F.W.,

Department of Surgery, School of Medicine - University of Nairobi,

Tel: 020-2726300

- Principal researcher:

Dr. Kipsang, Joseph Kibet,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 12471-20100,

Nakuru.

Mobile phone: 0724768850

Part II: Consent certificate:

I.....freely give consent of myself or for my proxy (Name.....) to take part in the study conducted by Dr. Kipsang, Joseph Kibet, the nature of which has been explained to me by him and/or his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to me or my proxy. The results of the study may directly be of benefit to me or my proxy and may assist in the management of cellulitis.

.....

Signature/left thumb print (Participant/Next of kin)

Date.....

Day/Month/Year

Statement by the witness if participant is illiterate

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness.....

Signature of witness.....

Date.....

Day/Month/Year

Part III: Assent form for minors (Below 18 years)

Ifreely agree to participate in the research being done by Dr. Joseph Kipsang on limb cellulitis. I have been given adequate explanation about the disease and its treatment. I have allowed my parent/guardian to sign on my behalf. I understand that I can opt out of the research at any time without my treatment being affected in any way. The outcome of the research may directly aid in better management of my condition or that of other patients with the same conditions.

Thumb print of participant if illiterate (a witness must sign below)

Part IV: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromises the care given.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate treatment of cellulitis.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher or assistant taking consent.....

Signature of researcher or assistant taking consent.....

Date.....

Day/Month/Year

FOMU YA IDHINI

Kiswahili version

I. Sehemu ya kwanza –Maelezo:

Mimi ni Dkt. Kipsang, Joseph Kibet, kutoka Idara ya Upasuaji ya Shule ya Utabibu – Chuo Kikuu cha Nairobi (University of Nairobi). Ninafanya utafiti kuhusu, “Utumizi wa kufunga katika kutibu ugonjwa wa selulaitisi ukilinganishwa na kutumia dawa pekee katika hospitali kuu ya Kenyatta.”

Utumizi wa kufunga katika kutibu selulaitisi inaweza kuleta madhara fulani ikiwemo gharama ya kununua kitambaa ; madhara ukitumiwa kwa ugonjwa wa mishipa ya damu na kukosekana kwa ustaarabu katika utumizi wake.

Utahitajika kupiga simu kwa mtafiti mkuu ukiwa na shida yoyote wakati wowote. Ukiwa na madhara yoyote kutokana na matibabu haya utapiga simu kwa wa simamizi wa utafiti ambao watawajulisha kitengo cha utafiti na Maadili cha Chuo Kikuu Cha Nairobi na Hospitali Kuu ya Kenyatta. Madhara yote yata shughulikiwa ipasavyo.

Ningependa kukuchagua wewe ama mgonjwa wako katika utafiti huu wangu.

Lengo langu ni kuchunguza utumizi wa kufunga katika kutibu ugonjwa wa selulaitisi ukilinganishwa na ule wa kutumia dawa pekee. Katika utafiti huu utatakiwa kutoa taarifa yako binafsi na taarifa kuhusu ugonjwa wa selulaitisi unao uugua. Utakaguliwa na mimi au msaidizi wangu utakapo onekana mara ya kwanza alafu kila siku kwa siku mbili zitakazo fuata. Huu ukaguzi uta jumlisha kupimwa kwa miguu au mikono yako. Damu itachukuliwa na kuchunguzwa katika maabara kwa mujibu wa kupima hali ya chembechembe za damu. Hii itasaidia katika kukutibu . Habari zote zitakazo kusanywa zita shughulikiwa kwa siri na hazita sambazwa ila tu kwa ruhusa kutoka kwa kamati ya maadili na utafiti ya Chuo Kikuu cha Nairobi na Hospitali Kuu ya Kenyatta.

Sababu ya utafiti huu ni kuchunguza utumizi wa kufunga ikilinganishwa na kutumia dawa pekee katika kutibu ugonjwa wa selulaitisi.

Kuhusika kwako kwenye utafiti huu hauna malipo yoyote ila ni kwa hiari yako mwenyewe na pia unaweza kujiondoa kwa utafiti huu wakati wowote bila kuathiri matibabu yako katika Hospitali Kuu ya Kenyatta.

Naomba mimi ama msaidizi wangu tukuulize maswali ambayo yatajibiwa kwa fomu maalum. Habari yote ambayo uta tuarifu ni ya siri kati yako nasi watafiti na haita enezwa kwa watu wengine.

Unaweza kuuliza maswali yoyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu kwa mtafiti mkuu ama mwenyekiti wa idara ya upasuaji katika chuo kikuu cha Nairobi ama msimamizi wa utafiti huu ukitumia nambari za simu zifuatazo:

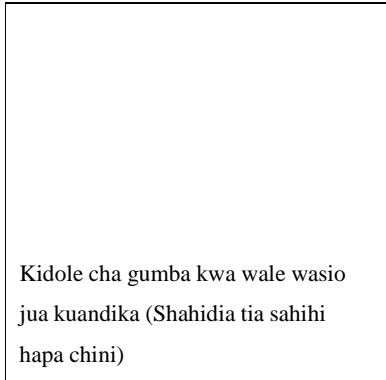
- Katibu, Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi na Hospitali Kuu ya Kenyatta. Sanduku la Posta 20723 KNH, Nairobi 00202. Nambari ya simu 726300-9.
- Mwenyekiti, Idara ya Upasuaji ya Chuo Kikuu cha Nairobi. Sanduku la Posta 19676 KNH Nairobi 00202. Nambari ya simu: 020-2726300.
- Wasimamizi wa utafiti, Chuo kikuu cha Nairobi;
 - Profesa Khainga, S.O. Nambari ya simu: 020-2726300.
 - Daktari Nangole. Nambari ya simu: 020-2726300.
- Mtafiti mkuu;
 - Daktari Kipsang, Joseph Kibet, Idara ya Upasuaji ya Shule ya Utabibu–Chuo kikuu cha Nairobi, Sanduku la Posta 12471, Nakuru (20100). Nambari ya simu: 0724768850.

II. Sehemu ya pili-Idhini:

Mimi (Jina).....kwa hiari yangu ama kwa hiari ya mgonjwa wangu (Jina la Mgonjwa)..... nime kubali kushiriki katika utafiti huu unaofanywa na Daktari Kipsang, Joseph Kibet kutokana na hali ambazo nime elezwa nasio kwa malipo ama shurutisho lolote.

Nime elewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu ninayopata ama anayopata mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na ya weza kusaidia kwa matibabu ya ugonjwa wa selulaitisi katika Hospitali kuu ya Kenyatta.

.....
Sahihi/ ama alama ya kidole cha gumba katika sanduku
Tarehe.....
Siku/ Mwezi/ Mwaka



Jina la shahidi.....
Sahihi.....Tarehe.....
.....
(Siku/Mwezi/Mwaka)

III. Sehemu ya tatu – Idhini ya walio chini ya miaka kumi na nane:

Mimi..... nakubali kwa hiari yangu bila kushurutishwa kushiriki katika utafiti unaofanywa na Daktari Kipsang kuhusu selulaitisi. Nime elezwa ya kutosha kuhusu ugonjwa huu na maswali yangu kujibiwa ipasavyo. Nime mruhusu mzazi wangu/msimamizi wangu kuweka sahihi kwa niaba yangu. Nime elewa kuwa naweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuadhiri kwa vyovyote vile matibabu yangu katika hospital ya Kenyatta. Matokeo ya utafiti huu yaweza kusaidia kwa kutibu ugonjwa wangu au wa wengine walio na ugonjwa wa selulaitisi.

IV. Sehemu ya nne- Dhibitisho la mtafiti:

Hii ni kuidhinisha ya kwamba nime mueleza mshiriki ama msimamizi wake kuhusu utafiti huu na pia nime mpa nafasi ya kuuliza maswali. Nime mueleza yafuatayo:

- Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha yake kamwe.
- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuadhiri matibabu anayo pata katika hospitali kuu ya Kenyatta.
- Habari ambazo ata peana hazitasambazwa hadharani bila ruhusa kutoka kamati ya maadili na utafiti ya Chuo Kikuu cha Nairobi na Hospitali Kuu ya Kenyatta.

Jina la mtafiti ama msaidizi wake.....

Sahihi.....

Tarehe.....

(Siku/Mwezi/Mwaka)

APPENDIX 5: LETTER OF APPROVAL FROM ERC/KNH



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



KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke



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

Ref: KNH-ERC/A/305

Link: www.uonbi.ac.ke/activities/KNHUoN

10th September 2014

Dr. Kipsang Joseph Kibet
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Kibet

RESEARCH PROPOSAL: OUTCOME OF COMPRESSION THERAPY AS AN ADJUNCT VERSUS STANDARD TREATMENT IN THE MANAGEMENT OF LIMB CELLULITIS AT KENYATTA NATIONAL HOSPITAL (P374/06/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 10th September 2014 to 9th September 2015.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- c) Death and life threatening problems and severe 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.
- d) 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.
- e) 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*).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- g) 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 www.uonbi.ac.ke/activities/KNHUoN.

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 Chair, KNH/UoN-ERC
 The Assistant Director, Health Information, KNH
 The Dean, School of Medicine, UoN
 The Chairman, Dept. of Surgery, UoN
 Supervisors: Prof. Khainga.S.O, Dr. Nangole E.W.