PATTERN OF OCULAR FINDINGS AND CONJUNCTIVAL SWAB POSITIVITY IN PATIENTS WITH CORONAVIRUS DISEASE-19 AT KENYATTA NATIONAL HOSPITAL IN KENYA

BY

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A dissertation submitted in partial fulfilment of the requirements for Master of Medicine in Ophthalmology, Faculty of Medicine, Department of Ophthalmology, University of Nairobi

DECLARATION

I certify that this thesis proposal is my original work and that it has not been submitted for a degree at any other university.

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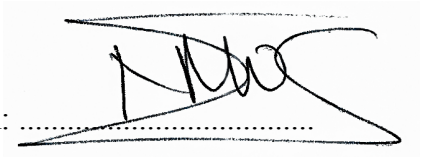
Sign:  Date: 24/04/2023

APPROVAL

With our consent as supervisors, this thesis proposal has been submitted for examination.

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DEDICATION

I dedicate my dissertation work to my loving husband, Said, who has been my rock during the challenges of graduate school. Special gratitude to my dear parents, Mustafa and Amina, who have always prayed for my success and helped raise my children during this time. I also dedicate this work to my best cheerleader, my sister Salwa.

Thank you, my love for you all can never be quantified. Allah blesses you.

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LIST OF ABBREVIATIONS

CDC… .....Centers for Disease Control

COVID-19…..... Corona Virus Disease 2019

CPAP….....Continuous Positive Airway Pressure

CWS..... Cotton Wool Spots

EOMM… ..... Extraocular Muscle Motility

HDU…..... High Dependency Unit

ICD-11… ..... International Classification of Disease 11

ICU…..... Intensive Care Unit

IDU… .....Infectious Disease Unit

KNH..... Kenyatta National Hospital

MERS-CoV…..... Middle east respiratory syndrome coronavirus

NHPL..... National Health Public Laboratory

PCR..... Polymerase Chain Reaction

RT-PCR.....Reverse Transcriptase Polymerase Chain Reaction

SARS.....Severe acute respiratory syndrome

SARS-CoV-2… ....Severe acute respiratory syndrome coronavirus 2

SEC .....Smart Eye Camera

SPSS..... Statistical Package for the Social Sciences

UoN..... University of Nairobi

VA..... Visual Acuity

VTM…..... Viral Transport Media

WHO..... World Health Organization

ABSTRACT

Study background: On 11th March 2020, Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) which causes Corona Virus disease-2019 (COVID-19) was declared a global pandemic. Ocular signs have been documented in several studies conducted outside of East Africa, in addition to usual symptoms like fever, cough, dyspnea, and other respiratory symptoms. This study aimed at understanding the range of findings in the eyes of those infected with COVID-19 in Kenya and provides a reference for other clinicians.

Objectives: To determine the pattern of ocular findings and positivity of conjunctival swab RT-PCR in individuals with COVID-19 in a Kenyan Population.

Material and Method: The study employed cross-sectional design conducted in Kenyatta National Hospital (KNH), including KNH's Infectious Disease Unit (IDU) to the patients that tested SARS-CoV-2 positive by Polymerase Chain Reaction (PCR). They were interviewed using a structured questionnaire. Anterior segment examination was performed using a Smart Eye Camera (SEC) and posterior segment examination by indirect ophthalmoscope. Conjunctival swabs were collected for PCR analysis. The data were entered into and analysed using SPSS software package version 25.0.

Results: A total of 70 patients (27 male and 43 females) with a mean age of 39.1 (SD 12.8) were examined. The most common ocular symptoms were grittiness (36%), itchiness (24%), and blurred vision (17%). Ocular findings included hyperemia (36%), follicular reaction (37%), epiphora (4%), and episcleritis (1%) in the anterior segment. Few patients were found to have CWS (7%), microvascular retinal haemorrhages (2%), Vitreous haemorrhage (1%), and exudates (1%) in the posterior segment. The conjunctival positivity rate was at 1.4%.

Conclusion: COVID-19 patients were found to have ocular findings but the conjunctival positivity rate was low. However, prevention of possible transmission via ocular secretions is still recommended.

1. INTRODUCTION AND BACKGROUND

On March 11th 2020, COVID-19 was declared a global pandemic, after rapidly spreading across the globe. SARS-CoV-2 is the virus that was first recognised in a few patients who presented with atypical pneumonia. It was associated with the seafood market in Wuhan China [1].

On 23rd March 2021, approximately a year after SARS-CoV-2 was proclaimed to be a pandemic; there were a total of 124 million reported cases, 70.6 million recovered and 2.74 million deaths reported worldwide [2]. On 12th March 2020, Kenya reported the first case of COVID-19[3]. By May 2021, Kenya had reported a total of 160,422 confirmed cases and 2763 deaths[2].

Diagnosis of infection is made using laboratory tests while the diagnosis of a disease is made using clinical signs and symptoms. The clinical diagnosis of COVID-19 has been shown to pose a challenge as there are no specific pathognomonic features of the disease. A wide range of features have been reported; from coughs, shortness of breath, sore throats, and haemoptysis in the respiratory system to diarrhoea, vomiting, and abdominal pains in the gastrointestinal system. Also reported to have renal features [4] and affects the central nervous system[5].

Many COVID-19 patients have been reported to have contracted Conjunctivitis, both as an early feature and during in- patient management of respiratory failure[6]. Other reported ocular features are dry eyes, foreign body sensation, itching, blurred vision, chemosis, and photophobia[4]. Further reports showed that ophthalmologists get infected during routine clinical practice. This has led to the notion that mucus membranes of the eyes could be a gateway for SARS-CoV-2 entry into the body after being in contact with the viral particles scattered as aerosols, thus having serious public health implications[6, 7].

Human losses do occur due to COVID-19 and may include highly trained professionals such as our first responders. Therefore, it is crucial to understand the types of ocular findings associated with SARS-CoV-2 infection to help clinicians make a better and faster diagnosis as most clinical research on COVID-19 has focused mainly on respiratory manifestations[4].

This study aimed at providing the baseline information on COVID-19 findings in eyes of Kenyan patients.

2. LITERATURE REVIEW

2.1 Historical perspective

Coronaviruses were initially not regarded to be highly infectious to human beings. They were reported to merely result in mild disease in healthy human beings. However, in 2002 and 2003, the first coronavirus outbreak was reported in Guangdong province in China of severe acute respiratory syndrome (SARS) which was found to have originated from bats and was transmitted to humans via market civets. In 2012, a second highly infectious coronavirus, the Middle East respiratory syndrome coronavirus (MERS-CoV) surfaced in the Arabian Peninsula and was also found to originate from bats and transmitted directly to humans by dromedary camels[8].

Furthermore, on 12th December 2019, the most recent outbreak of coronavirus was first reported in Wuhan, a city in China. Li Wenliang, an Ophthalmologist working at Wuhan Central Hospital, was among the first to recognize the COVID-19 outbreak. He warned his colleagues on a private social media platform. Shortly after, he picked up the virus from an asymptomatic glaucoma patient and on thirty first January 2020, he tested positive for the virus. On 7th February 2020, Li Wenliang died from COVID-19 at the age of 33 years in Wuhan Central Hospital [9, 10].

As the virus spread, Thailand became the first country to report COVID-19 cases on January 13, 2020, followed by Japan on January 16, 2020. On 23rd January 2020, Wuhan and other cities in the near vicinity were placed under lockdown to reduce the spread. Unfortunately, the virus found its way outside China into Asia, Europe, North America, South America, Africa, and Oceania and was eventually declared a global pandemic on March 11th, 2020[11].

On 12th March 2020, SARS-CoV-2 found its way into Kenya from the United States of America, and the case was confirmed by the Kenyan Ministry of Health through the National Public Health Laboratories in their National Influenza Centre Laboratory[3].

2.2 Aetiology

Coronaviruses are from the *Coronavirinae* subfamily in the *Coronoviridae* family and the *Nidovirales* order. There are four genera in the subfamily; they are *Alpha-, Beta-, Gamma-* and *Delta* coronaviruses. The *Gammacoronavirus* and *Deltacoronavirus* affect birds but some also affect mammals. *Alphacoronavirus* and *Betacoronavirus* exclusively infect mammals and commonly affect the respiratory system in humans and the gastrointestinal system in animals[8]. COVID-19 is a new coronavirus with a linear single-stranded positive-strand RNA genome that belongs to the Coronavirus family, Betacoronavirus genus, and Sarbecovirus subgenus, in line with a number of studies[12]. All coronaviruses that have affected humans have been seen to have animal origins. Domesticated animals play a fundamental role as secondary hosts thatallow transmission of the virus from its original host to humans. As of March 2019, *Jie Cui et al* reported that 7 out of 11 *Alphacoronavirus* species and 4 out of 9 *Betacoronavirus* species were associated with bats, hence concluding that the likely reservoirs of *alphacoronavirus* and *betacoronavirus* are bats[8].

2.3 Transmission

The main mode of transmission of SARS-CoV-2 is via respiratory droplets. A healthy individual can be infected if they get in contact with the infected individual or their belongings including but not limited to their clothing or doorknobs. It is suspected to be airborne and transmitted through aerosols. However, the potential of infection through ocular secretions is currently unknown, and how SARS-CoV-2 accumulates in ocular secretions remains unclear. Hypotheses include nasolacrimal duct migration from the nasopharynx, hematogenous dissemination through the lacrimal gland, or direct inoculation of the ocular tissues by respiratory droplets or aerosolized virus particles. By wearing masks and keeping a 2-meter distance between individuals, its spread can be minimised. Unfortunately, there are still some challenges to this, for example, (i) infection period is uncertain (ii) individuals may be asymptomatic and still be able to spread the virus[5] (iii) rapid mutation of SARS-CoV-2 has resulted in the ineffectiveness of some vaccines developed up to date against some new variants [13,14].

The incubation period of SARS-CoV-2 is between 1-12 days[5].

2.4 Clinical presentation

COVID-19 patients have been shown to present with fever, cough, and fatigue at the onset of the illness. Other features seen are the production of sputum, dyspnea, haemoptysis, diarrhoea, headaches, and lymphopenia. Suspicious chest CT scans showed pneumonia and other abnormal features such as RNAemia (blood detection of SARS-CoV-2 RNA), acute cardiac injury, acute respiratory distress syndrome, and incidence of ground-glass opacities that may lead to mortality[15]. Studies done on ophthalmic features in COVID-19 patients have shown mixed findings. In Thailand, a study of COVID-19 patients found no ocular abnormalities after a thorough ocular examination that included corneal scraping. However, the same study found that visual manifestations of the condition are frequently overlooked by Thai physicians[16, 17.] Patients with COVID-19 have at least one ocular characteristic, according to a study conducted in Turkey. Hyperemia, epiphora, chemosis, episcleritis, increased secretion, and follicular conjunctivitis were among the illnesses observed. Itching, burning, grittiness, impaired vision, and, most commonly, photophobia are mentioned as symptoms[16, 18]**.** Patients with severe COVID-19 disease had a greater risk of conjunctivitis, according to a retrospective examination of COVID-19 patients in China. SARS-CoV-2 has also been identified in COVID-19 patients' tears[19, 2]. Cotton wool spots (CWS), tortuous arteries, microvascular bleeding, and hyper-reflective lesions on imaging have all been seen in persons without diabetes [21, 22]. The size of the retinal veins has been connected to the severity of the condition[22]. Other investigations, on the other hand, found no retinal manifestations[23].

3. JUSTIFICATION AND RATIONALE

This study was carried out to determine whether COVID-19 patients have ocular abnormalities and, if so, what types of ocular involvement they have. Tear PCR was employed in the early identification of infection because some studies have shown the presence of the coronavirus in the early phase of infected individuals' tears[24]. This data will be used as a reference in the future, and it could help clinicians detect the infection sooner.

No similar research had been conducted in Kenya, but there have been others reported abroad.

4. OBJECTIVES

4.1 Broad objectives

The objective of this study was to determine the pattern of ocular findings and positivity of conjunctival swab RT-PCR in individuals with COVID-19 in a Kenyan population.

4.2 Specific objectives

1. To document the pattern of ocular findings in individuals with COVID-19.
2. To determine the positivity of conjunctival swab RT-PCR among patients with COVID-19.

5. MATERIALS AND METHOD

5.1 Study design

This was a cross-sectional study.

5.2 Study area

The study was carried out in Kenyatta National Hospital (KNH) including the laboratory located in the Zarina Marina Daycare building and the COVID-19 isolation centre at KNH's infectious disease unit (IDU), which has an annex at Mbagathi County Referral Hospital.

KNH is Eastern and Central Africa's largest national teaching and referral hospital, with 1800 beds in the general wards, 209 beds in the private wing and 60 beds in the IDU. Mbagathi County Referral hospital has a 320-bed capacity. These 2 hospitals are located in Nairobi, the capital city of Kenya.

Patients were triaged in accident and emergency department, nasopharyngeal and oropharyngeal swabs were collected and samples sent to the laboratory. Some very sick patients were sent to high dependency unit (HDU) or intensive care unit (ICU), and some were stable to be sent to the wards. Medical patients were sent to IDU and surgical patients were isolated within the surgical wards. KNH also received COVID-19 confirmed cases from different health facilities, these patients were sent directly to IDU, HDU or ICU. There was also a group of patients who were found to have mild disease and did not warrant admission; these patients were sent to clinic 66 for further assistance.

5.3 Study population

This study included all patients who were positive for COVID-19 by RT-PCR and who were within the study area and had given informed consent.

5.4 Inclusion criteria

All patients who were 18 years and older, and had tested positive for COVID-19 by RT-PCR.

5.5 Exclusion criteria

Patients who were critically ill on ventilators were excluded from the study.

5.6 Sample size determination

The sample size was calculated using Fisher's Formula. No study has been conducted in Kenya to determine the prevalence of ocular findings among COVID-19 patients.

$$n = \frac{(Z^2 pq)}{d^2}$$

Where:

n = the desired sample size

Z = the standard normal deviate at the required confidence level

(95%=1.96)

p = estimated prevalence of ocular manifestation in COVID-19 (21.5%) as per *Bostanci et al*[18]

q =1-*p*

d = margin of error (0.1)

n= 63

Adding 20% for anticipated non-response

n = 75 patients

5.7 Sampling technique

Consecutive sampling was used in selecting study participants. COVID-19 patients were first identified from the laboratory database. This helped in narrowing it down to the exact location of the patients within KNH. Every COVID-19 patient admitted to KNH or attending clinic 66 to collect their results was included in this study. The sampling went on until the required sample size was attained.

5.8 Case definition

A case was defined as a patient who had laboratory-confirmed SARS-CoV-2 results and/or was clinically diagnosed via imaging.

5.9 Examination methods

The visual acuity (VA) was assessed using Snellen and Landolt's C chart. Testing visual acuity with a pinhole was done to rule out a refractive error in patients with vision less than 6/6. Extraocular muscle motility (EOMM) was assessed using a gloved finger as the target of focus. The anterior segment was examined using a Smart Eye Camera (SEC) (*Figure 1* below). SEC is a medical device from Japan that has a Smartphone attachment that enables anterior segment examination. With 3 types of light (Slit/White-diffused/Blue-diffused) available, it has the capability to take clear images from the eyelids, conjunctiva, cornea, iris, and crystalline lens. It has been proven to have equal performance as the conventional slit lamp microscope, hence capable of diagnosing any anterior segment disease[25].

Tropicamide/phenylephrine eye drops were instilled to dilate the pupil and posterior segment examination was assessed using a 20D lens and an indirect ophthalmoscope. The examination findings were entered into the data collection tool (Appendix 1).

Figure 1

5.10 Conjunctival Swab

Without instilling local anaesthetic drops, a smear from the conjunctival mucosa was collected from the lower fornix of one eye using the Puritan eye swabs (*Figure 2* below) and inserted in the Viral Transport Media (VTM) then stored in a cooler box for transportation to the National health public laboratory (NHPL) for PCR analysis.

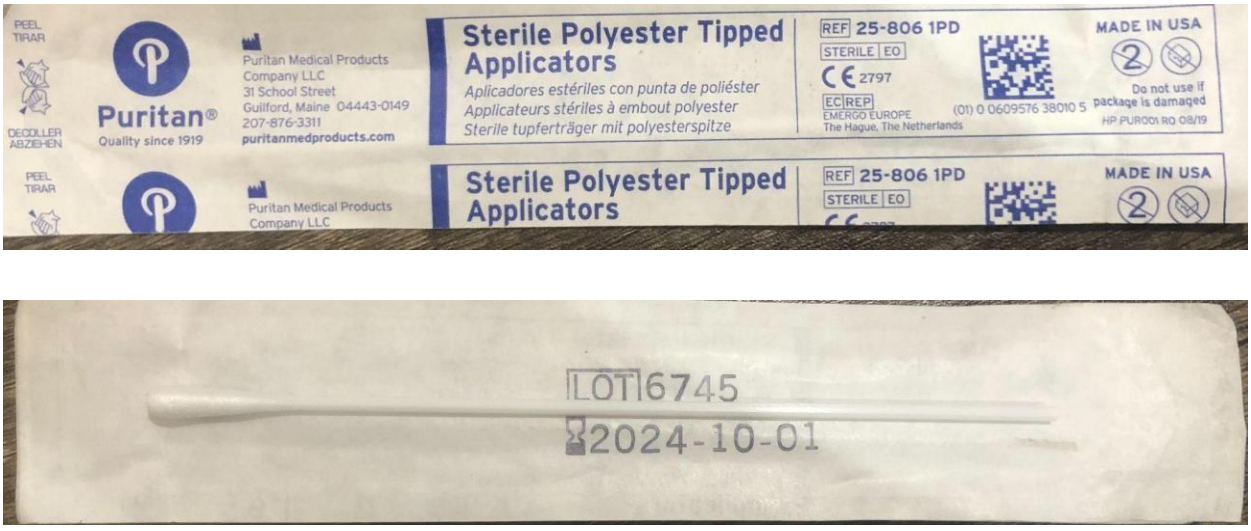

Figure 2

5.11 Safety procedure

The researcher received the first and the second dose of the vaccine against COVID-19; wore appropriate personal protective equipment and used a voice recorder to document the patients' findings to avoid contamination.

As a precautionary measure, the examination was set in a well-ventilated area and all the patients had N-95 or K95 or surgical masks worn. Similarly, the patients were requested to refrain from speaking during the examination process. The process was carried out one patient at a time in their respective wards and clinic.

The use of a direct ophthalmoscope was prohibited, and instead, the fundus was examined using a 20D lens and an indirect ophthalmoscope. All the equipment and the bottle of eye drops used were thoroughly wiped down with 70% alcohol disinfectant solution after each patient.

5.12 Data collection

For patients who agreed to participate in the study, identification numbers were assigned to guide the researcher during data exploration and input. A structured questionnaire was used to collect the data. It included the participants' biodata, symptoms, time of onset, pre-existing clinical condition, current treatment, ocular signs, and whether tear sampling for PCR was done.

5.13 Quality assurance protocol

To ensure the reproducibility of this study several techniques were carried out, this included (i) clear documentation on any changes within the data collection protocol (ii) clear documentation and handling of collected data (iii) accurate clinical skills (iv) conjunctival samples collected were transported in a sealed biohazard cooler box to the NHPL together with a transport manifest (v) conjunctival samples were received and handled by qualified personnel.

5.14 Ethical consideration

Ethical approval was sought from the KNH/UON research and ethics committee, NHPL, and KNH Research and Resource Centre. Data collection and analysis were not commenced before ethical approval. Informed written consent was sought and only consenting patients were enrolled in the study. Confidentiality was assured throughout the study by using the study identification numbers.

5.15 Data analysis

Data was checked for completeness and free of error prior to entry into the Microsoft Excel 2017 spread sheet. Later, it was exported to the Statistical Package for Social Sciences version 25 for analysis. Demographic and clinical characteristics of the patients were analysed and presented as frequencies and percentages for categorical and as means with standard deviation for continuous data. The pattern of ocular findings and positivity of conjunctival swab RT-PCR were presented as frequencies and percentages. The findings were also presented as bar graphs and some as tables.

6. RESULTS

Seventy-five patients who tested positive for SARS-CoV-2 by RT-PCR were selected from the laboratory and included in the study. Seventy patients (93.3%) agreed to be interviewed, and examined and conjunctival sample to be collected. The other five patients were excluded from the study due to the following: Two patients declined collection of the conjunctival sample, one patient refused instillation of tropicamide/phenylephrine drops, one other patient declined to have fundoscopy done, and one patient consented but was later excluded from the study as per the husband's request.

Forty (57.1%) out of the seventy patients complained of ocular symptoms and fifty-five patients (78.6%) had at least one ocular finding.

6.1 Demographic characteristics

Table 1: Demographic characteristics of the studied patients (n=70)

Variable		Number of patients	Percent
Age	18 – 25	9	12.9
	26 – 35	25	35.7
	36 – 45	17	24.3
	46 – 55	8	11.4
	Above 55	11	15.7
Gender	Male	27	38.6
	Female	43	61.4
Residence	Urban	66	94.3
	Rural	4	5.7

The Male to Female ratio was 1:1.6. The mean age of the patients was 39.1 (SD 12.8) years. The median age was 36.0 (IQR 30.0 - 46.0) years.

6.2 Past Medical History

Table 2: COVID-19 Immunization status of the studied patients (n=70)

		Number of Patients	Percent
1st Dose Vaccine	No	11	15.7
	Yes	59	84.3
Total		**70**	**100**
2nd Dose Vaccine	No	13	18.6
	Yes	57	81.4
Total		**70**	**100**

Most of the patients (84.3%) had received the first dose of COVID-19 vaccine, and 57 patients (81.4%) had received the second dose.

Table 3: Current Treatment History

	Number of Patients	Percent
Treatment	59	84.3
No Treatment	11	15.7
Total	**70**	**100**

Among these 38 patients (54.3%) were on antibiotics, 31 (44.3%) on analgesics, 8 (11.4%) on corticosteroids, and 5 (7.1%) on antihistamines. Other reported treatments were vitamin C, Non-steroidal anti-inflammatory drugs, and zinc.

Table 4: Types of Comorbidities (n=70)

Comorbidities	Number of Patients	Percent
No Comorbidities	33	47.1
Hypertension	13	18.6
Diabetes	6	8.6
Asthma	5	7.1
Anaemia	1	1.4
Vaginal Carcinoma	1	1.4
Liver Cirrhosis	1	1.4
Cerebral Vascular Accident	1	1.4
Rheumatic Heart Disease	1	1.4
Peptic Ulcer Disease	1	1.4
Intestinal Perforation	1	1.4
Ocular Comorbidities	6	8.6
TOTAL	**70**	**100**

Some patients were found to have pre-existing medical conditions such as hypertension, diabetes, and asthma.

6.3 Symptoms

Table 5: Symptoms of the studied patients (n=70)

Symptoms	Number of Patients	Percent
Cough	57	81.4
Fatigue	57	81.4
Fever	47	67.1
Headaches	34	48.6
Backaches	12	17.1
Chills	12	17.1
Sore Throat	10	14.3
Diarrhea	9	12.9
Joint pains	9	12.9
Vomiting	8	11.4
Runny nose	8	11.4
Chest pains	7	10.0
Dyspnea	6	8.6
Sneezing	6	8.6
Hypogeusia	3	4.3
Ocular Symptoms	40	57.1
No Symptoms	3	4.3

Cough and fatigue were found to be the commonest general symptoms followed by fever then headaches.

6.31 Ocular Symptoms

Table 6: Ocular symptoms of the studied patients (n=70)

Symptoms	Number of Symptoms Present
No symptoms	30
Grittiness	25
Blurred vision	12
Itchiness	17
Photophobia	7
Redness	11
Discharge	4
Pain on ocular movement	6
Tearing	6
TOTAL	**118***

*N was more than 70 as some had more than one symptom.

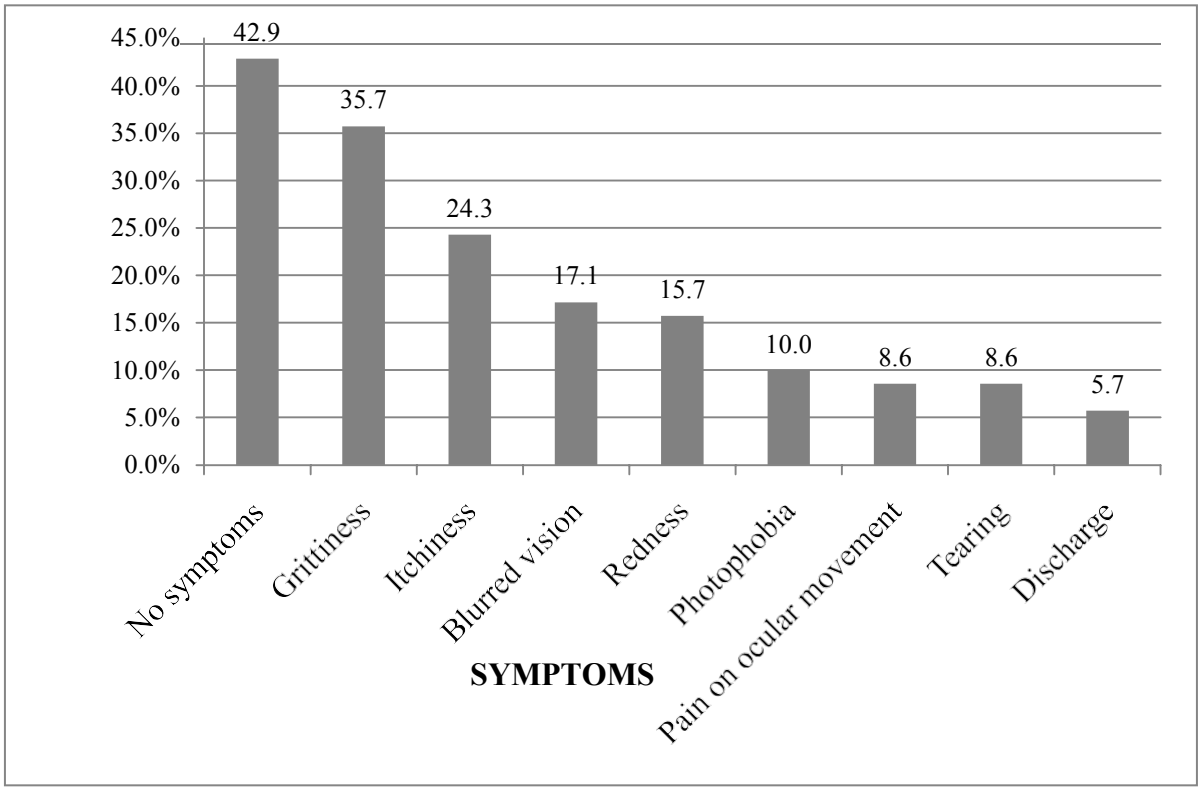

Figure 3: Ocular symptoms in the studied patients

The commonest ocular symptoms reported were grittiness, itchiness, and blurred vision. Eleven (15.7%) patients reported redness, 7 (10%) photosensitivity, 6 (8.6%) tearing, and 6 (8.6%) had pain in eye movement and 4 (5.7%) patients reported discharge.

6.4 Visual Acuity

Majority (98.6%) of the patients had visual acuity of 6/12 and better in the better eye except one patient who had moderate visual impairment as per the International Classification of Diseases 11 (ICD-11).

Table 7: Visual acuity with Pinhole (n=140)

Visual acuity	**Number of Eyes**	**Percent**
6/5	2	1.4
6/6	112	80
6/9	20	14.3
6/12	3	2.1
6/18	1	0.7
6/24	1	0.7
HM	1	0.7
TOTAL	**140**	**100**

Most (97.9%) of the eyes examined had normal visual acuity.

6.5 State of Adnexa

Table 8: Adnexal Findings in the studied Eyes (n=140)

Signs	Number of Eyes
No Signs	44
Follicular reaction	52
Hyperemia	50
Discharge	14
Epiphora	6
Hyperpigmentation	2
Swelling	1
Chemosis	0
TOTAL	**169***

*N was more than 140 as some eyes had more than one finding.

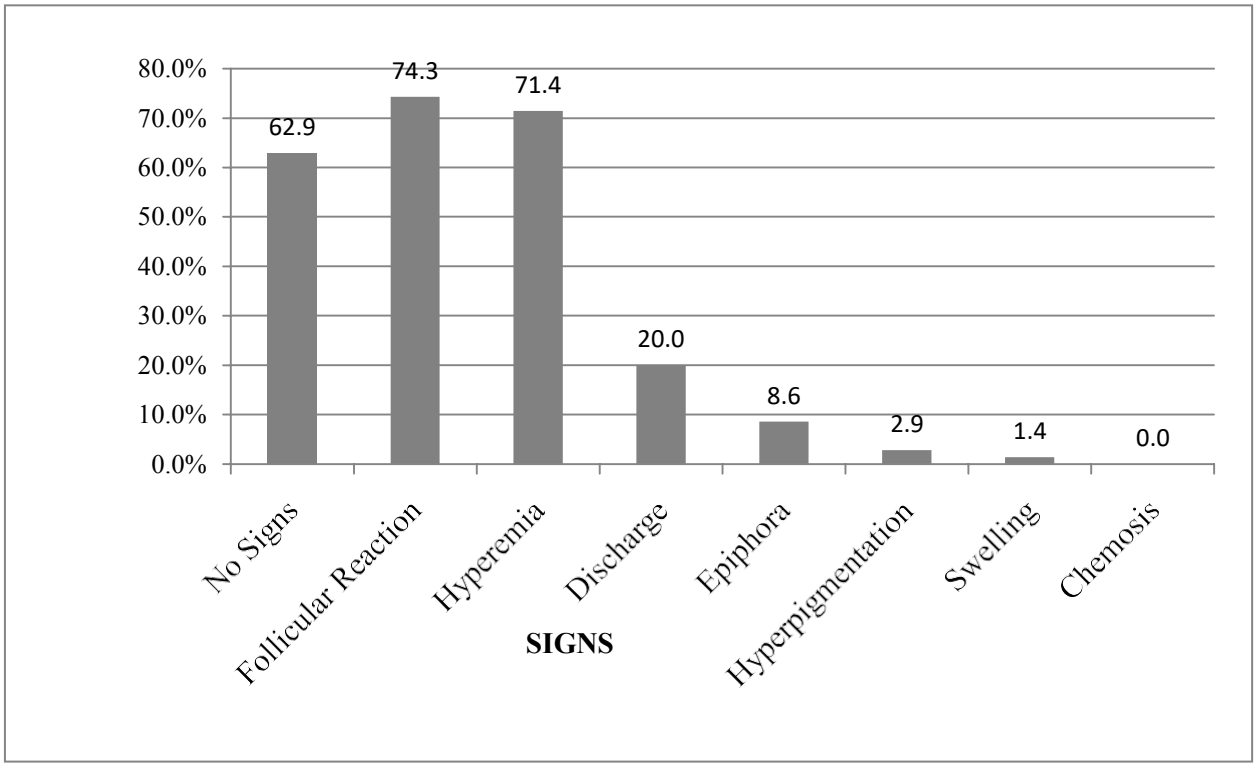

Figure 4: Adnexal Findings in the studied patients.

Of the 140 eyes, the commonest finding was follicular reaction in 52 eyes (74.3%) and Hyperemia in 50 eyes (71.4%). .

6.6 State of Anterior Segment

Table 9: Anterior Segment Findings in the studied Eyes (n=140)

Findings	Number of Eyes	Percent
No signs	120	85.7
Cataract	16	11.4
Jaundice	4	2.9
Episcleritis	2	1.4
TOTAL	**142***	**101***

The majority of the 140 eyes did not have anterior segment findings (85.7%). However, 2 eyes (1.4%) had Episcleritis, 4 eyes (2.9%) were found to have jaundice and 16 eyes (11.4%) had cataracts.

*N was more than 140 as some eyes had more than one finding.

6.7 State of Posterior Segment

Table 10: Posterior Segment Findings in the studied Eyes (n=140)

Findings	Number of Eyes	Percent
No Sign	122	87.1
Cotton wool spots	10	7.1
Microvascular haemorrhages	3	2.1
Viitreous haemorrhage	2	1.4
Exudates	1	0.7
Tortuous Vessels	2	1.4
Dilated Vessels	0	0.0
TOTAL	**140**	**100**

The majority of the patients (87.1 %.) had no posterior segment findings. Very few patients were found to have CWS (7.1%), microvascular retinal haemorrhages (2.1%), Vitreous haemorrhage (1.4%), tortuous vessels (1.4%) and exudates (1%).

6.8 Conjunctival Positivity Rate

Table 11: Positivity Rate for RT-PCR for SARS-CoV-2 in Conjunctival Swab

	Number of Patients	**Percenta**
Positive	1	1.4
Negative	69	98.6
TOTAL	**70**	**100**

Only one patient (1.4%) was positive for RT-PCR for SARS-CoV-2 in conjunctival swab.

7. DISCUSSION

In this study, the signs and symptoms of 70 COVD-19 patients, both hospitalized and non-hospitalized were reviewed, with a special focus on ocular findings. Conjunctival sampling was carried out in all patients. The majority of this study patients were non-hospitalised and fully vaccinated (81.5%). This may have led to a less severe form of the disease and many of the used different regimes to self medicate. As a result, it may have caused a less pronounced observation in the ocular findings and positivity of the conjunctival swab RT-PCR.

7.1 Distribution by Age and Sex

The mean age of the patients was 39.1 (SD 12.8) years. The median age was 36.0 (IQR 30.0 - 46.0) years, with the minimum age being 18 years and the maximum 72 years. This does not compare favourably with other studies. *Wu et al* in China found a median age of 65.8 ± 16.6 years; *Cavalleri et al* found a mean age of 68.2 ± 13.4 years; *Abrishami et al* found a mean age of 62.6 ± 15 years. However, *Bostanci et al* had an almost similar mean age of 39.9 ± 21.9 [6, 18, 19]. Respiratory illnesses are found to affect chronically ill, older patients more than healthy, young adults and tend to be more severe[26]. Therefore, the younger age in this study could be explained by the fact that patients with severe disease in ICU/HDU setup were excluded as compared to the other studies; a majority of whom are expected to be in the older age groups.

Forty three (61.4%) were female with a Male to Female ratio of 1:1.6. This is similar to the Iranian study by *Nasiri et al* where Females comprised 55.3% of cases (1:1.2). Other studies were not favourable to this. *Wu et al* in China discovered 65.8% of cases (1.9:1) comprised of males; *Cavalleri et al* found 68.0% of cases to be males (2.1:1); *Bostanci et al* found 58.1% of cases to be males (1.4:1). *Abrishami et al* discovered 54.2% of cases to be males (1.2:1)[4, 6, 16, 18, 19].

The distribution by sex (a slightly higher female proportion) in this study could be explained by the type of selected study population, that is, not the critically ill. There is a longstanding stereotype that men don't seek medical assistance easily unless seriously ill, they are supposed to be tough and full of machismo. This was supported by a study conducted by the Centers for Disease Control (CDC), which reported that women are 33% more likely to seek medical assistance than men [27].

7.2 Symptoms

The common complaints at the onset of the disease were cough (81%), fatigue (81%), fever (67%), and headaches (49%) which are consistent with the description of COVID-19 as a viral illness. Other noteworthy complaints include backaches (17%), chills (17%), sore throat (14%), runny nose (11%), chest pains (10%), and hypogeusia (4%) which are consistent with SARS-CoV-2 infection.

Forty (57%) of the patients had ocular complaints. Grittiness (dry eyes) was the most common ocular complaint in this current study (36%), this was followed by itchiness (24%), blurred vision (17%), and redness (16%). This is comparable with most of the findings in other studies, for example, *Nasiri et al* study and *Bostanci et al* study. It is postulated that stress to the ocular surface, such as infection, in this case, is a triggering mechanism of dry eyes[28]. This may further lead to itchiness, blurred vision, or redness as observed in this cohort. Other noteworthy findings in this current study are photophobia, pain in ocular movement, tearing, and discharge.

It is worth noting that 6 (8.6%) of the studied patients had a previous ocular history which included 1 (1.4%) patient who was on topical antibiotic drops for 1 week, 3 (4.3%) patients previously managed for allergic conjunctivitis in the past 1 year, 1 (1.4%) patient with a history of receiving intravitreal Aflibercept, and 1 (1.4%) with a history of refractive surgery.

7.3 Adnexa and Anterior Segment Findings

The most common ocular findings in this study were follicular reaction (37%) and hyperemia (36%). Epiphora (4%) and episcleritis (1%) were found in a few patients while chemosis was not reported. This was similar to several studies, for example, a study by *Bostanci et al* found that the most common ocular finding was hyperemia followed by epiphora then follicular reaction, with minimal cases reported of chemosis in 3.2% of patients and episcleritis in 2.2% of the patients[18]. *Abrishami et al* also discovered conjunctival hyperemia to be the most common finding but unlike this current study, they also detected chemosis in 15.5% of cases and tearing in 23.2% of cases which is contradicting the current findings. The reason for this discrepancy could be due to the severity of the disease as more than half of their patients had severe disease and most of whom were in an ICU set-up[16].

Another rare finding in this study was cataract that was seen in 11% of the eyes, this was similar to the study by *Abrishami et al* where they found 7.7% of the patients to have cataract. Nonetheless, this may also be a result of age as these cataracts were seen in the older age group (that is between the sixth to eighth decades of life); and not as a direct result of the COVID- 19 disease.

Jaundice was detected in 4 (3%) of the eyes, but was concluded to be a result of comorbidities in the studied patients; 1 patient was known to have hemolytic anemia and the other had liver cirrhosis.

7.4 Posterior Segment Findings

Some patients were found to have pre-existing conditions such as hypertension in 13 (18.6%) patients and diabetes in 6 (8.6%) patients. One of the patients was receiving intravitreal Aflibercept for the management of diabetic retinopathy and macular oedema.

Posterior segment findings in this study were cotton wool spots (CWS) in 7.1% of the eyes, retinal hemorrhages in 2.1% of the eyes, vitreous haemorrhage in 1.4% of the eyes, and exudates in 1% of the eyes. However, these were found among five patients who were on treatment for hypertension and diabetes mellitus. *Pirralgia et al* found no retinal manifestations among COVID-19 patients[23]. But *Sims et al* conducted a cross-sectional study where they were looking for retinal microvascular signs in COVID-19 patients. He detected microhaemorrhages in eight eyes, retinal vascular tortuosity in six eyes, and CWS in two eyes using colored fundus photography. In addition, *Invernizzi et al* also reported retinal hemorrhages in 9.25%, CWS in 7.4%, drusen in 11.1%, dilated veins in 27.7%, and tortuous vessels in 12.9% of the patients. However, in their study retinal specialists used fundus photos that were acquired with the Digital Retinography System (DRS) fundus camera and processed using an Automated Retinal image analyzer to assess the mean retinal vessels diameter[21, 22].

The rare comorbidities found in this study were asthma in 5 (7.1%) patients, 1 (1.4%) patient each with anaemia, vaginal carcinoma, cerebrovascular accident, liver cirrhosis, rheumatic heart disease, intestinal perforation, and peptic ulcer disease.

7.5 Conjunctival Secretions

In this study, viral RNA was detected in only 1 patient (1.4%) who also presented with features of viral conjunctivitis. This was comparable with a prospective study conducted by *Xia et al,* where tear and conjunctival secretions of 30 COVID-19 patients were analysed for viral RNA by RT-PCR. The virus was detected in only one patient who had conjunctivitis at the time of conjunctival sampling; hence it was proposed that the virus may only exist in the tear and conjunctiva of patients with conjunctivitis[29]. Similarly, *Loon et al* found tears in 3 out of 36 patients, who were suspected to have SARS-CoV-2, to test positive for PCR[24]. Additionally, another study detected conjunctival SARS-CoV-2 in 3 out of 121 patients[7].

Air leaks from oxygen masks or CPAP (Continuous Positive Airway Pressure) masks towards the eyes may sometimes be responsible for contamination of the sampled areas in patients without conjunctivitis yielding false positive results[6, 29].

Studies have shown that ocular symptoms related to COVID-19 are prevalent in the prodromal stages of the disease and the presence of the viral RNA in the conjunctiva may be transient after inoculation[6, 7].

7.51 Case Presentation

A forty-year-old female public health officer from Eldoret got tested for SARS-CoV-2 RNA as a routine procedure for travelling. She was not vaccinated. Nevertheless, there was a 2-day history of grittiness, itchiness, tearing, and redness prior to the onset of fevers that had started on the day of nasopharyngeal swab collection. She also reported having a history of being treated for allergic conjunctivitis 2 months prior but currently had no history of using systemic or ocular treatment. (It was important to note that, unlike this patient, most of the patients in this study had more than 3 days' history of general symptoms or ocular symptoms before presenting to a health facility and some had already self-medicated). Ocular examination revealed a normal visual acuity of 6/6 on both eyes and a free extraocular motility examination. Adnexal examinations revealed conjunctival hyperemia. Anterior and posterior segment examinations were within normal. A conjunctival sample was collected and she tested positive for SARS-CoV-2 infection via RT-PCR.

8. LIMITATIONS

a) A limitation that may have contributed to the low conjunctival positivity rate was: unlike in other studies where they collected tears, this current study collected conjunctival sample. The concentration might have been insufficient for RT-PCR detection of the virus, and therefore, the possibility of virus in the tears and conjunctiva in these patients cannot be entirely ruled out.

b) This study was conducted late at the tail end of the pandemic due to logistic reasons and thus may have contributed to the fewer symptomatic patients.

9. CONCLUSION

The common ocular manifestations in COVID-19 patients were grittiness, itchiness, blurred vision, follicular reaction, and hyperemia.

Based on these findings and other literature, the probability of SARS-CoV-2 present in the conjunctiva is low.

10. RECOMMENDATIONS

a) Recognition of ocular findings in combination with other systemic features could help improve the diagnosis and management of COVID-19 patients. Hence ophthalmologists could be part of the therapeutic team for comprehensive management of these patients.

b) The yield of conjunctival sampling is very low therefore not recommended as a routine test.

c) Despite the conjunctival positivity rate being low, it does not rule out that SARS-CoV-2 may be transmitted through the conjunctiva. Thus, prevention of possible transmission through ocular tissue is recommended as ophthalmologists may be the first health care workers encountered by these patients.

d) Since COVID-19 has been with us for a long time this study may provide a baseline for future interventions.

e) This study may also provide a baseline for future studies when new COVID-19 variants emerge or in patients who have long COVID (that is, post COVID conditions).

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12. APPENDIX

12.1 Budget Estimate

ITEMS	QUANTITY	PRICE IN KSH
Disposable protective gowns + shoe covers	20	8000
Disposable box of gloves	2	2000
Protective eyewear	2	2000
K95 masks	100	6000
Digital voice recorder + batteries	1	7000
Photocopy + printing questionnaires	80	5000
Printing + Binding book	4	11000
Cooler box + Ice pack	1	2000
TOTAL		**43000**

12.2 Study Tool

CODE: ……..

STUDY TOOL

BIODATA

Identification number: ……..

Age: …….

Sex: …….

Residence: ……

Occupation: …….

Time of onset: ……

Vaccination status: ……..

SECTION A
Do you have any of the following general symptoms?

	Yes	No
1. Fever		
2. Cough		
3. Fatigue		
4. Diarrhea		
5. Vomiting		
6. Others (specify) ……		

Do you have any of the following eye problems?

Yes No

1. Grittiness
2. Blurred vision
3. Itchiness
4. Photophobia
5. Redness
6. discharge
7. Others (specify) ……..

Are you currently on any treatment/medication? Yes No

If yes, specify …….

…….

SECTION B

PAST MEDICAL HISTORY

Do you have any of the following?

Yes No

1. Diabetes
2. Hypertension
3. Asthma
4. HIV/AIDS
5. Others (specify)…….

PAST OCULAR HISTORY

Do you have a history of previous eye disease /treatment?

Yes No

If yes, specify……..

SECTION C

I would like to perform an eye exam now?

	OD	OS
VA	…….	……..
VA with PH	…….	……
EOMM	……..	……

Lids:

1. Normal
2. Epiphora
3. Swelling
4. Discharge
5. Others (specify) …….

Conjunctiva:

1. Normal
2. Hyperemia
3. Chemosis
4. Episcleritis
5. Follicular reaction
6. Others (specify) ……

Cornea:

1. Clear
2. Opacification
3. Others (specify) …….

Sclera

1. Normal
2. Episcleritis
3. Others (specify)……...

OD OS

Anterior chamber

1. Normal
2. Flare
3. Cells
4. Others (specify)……

Iris

1. Normal
2. Others (specify)……

Pupil

1. Shape……
2. RTL

Lens

1. Clear
2. Cataract
3. Others (specify) ……..

Vitreous

1. Clear
2. Cells
3. Haemorrhage
4. Others (specify)……..

Retina

1. Cotton wool spots
2. Haemorrhage
3. Dilated vessel
4. Tortuous vessel
5. Others (specify) ……..

SECTION D

Mode of diagnosis:

	Date	Negative/Positive
Clinical diagnosis		
Blood test (PCR)		
Nasopharyngeal swab (PCR)		
Conjunctival swab (PCR)		

Any other investigation done

1. FHG?

- Findings:

  ……

2. Imaging?

- Type: …….
- Findings: ……

3. Others?

- Findings: ……

12.3 Consent

12.31 Explanation

Coronavirus disease-19 is an infectious disease resulting from SARS-CoV-2 infection. Apart from common symptoms like fevers and respiratory symptoms, ocular manifestations have been reported. This study will determine the prevalence and pattern of ocular manifestations and the positivity rate from conjunctival swab RT-PCR in individuals with COVID-19. This will provide a reference for other clinicians.

The study procedure involves a voice recorded interview, visual acuity testing using a chart, and ocular examination using a smart eye camera for the anterior segment. The eyes will be dilated with tropicamide drops and fundoscopy will be done. This will be followed by conjunctival swabs which will be collected for PCR testing after instilling topical anesthesia. There are no significant risks apart from increased light sensitivity and blurring of vision for 3-4 hours caused by tropicamide.

Participation in this study is completely optional, and no financial or material incentives are anticipated. Any eye disease diagnosed will be managed accordingly and any case requiring specialized eye treatment will be sent to the KNH eye clinic for further management. Suspicious findings will be photographed using the smart eye camera. Confidentiality of records shall be maintained.

***Maelezo ya Idhini*:**

Ugonjwa wa Coronavirus-19 ni ugonjwa wa kuambukiza unaotokana na maambukizo ya SARS-CoV-2. Mbali na dalili za kawaida kama homa na dalili za kupumua, udhihirisho wa macho umeripotiwa. Utafiti huu utaamua kuenea na muundo wa udhihirisho wa macho na kiwango cha upendeleo kutoka kwa usufi wa kiwambo cha RT-PCR kwa watu walio na COVID-19. Hii itatoa rejea kwa matabibu wengine.

Utaratibu wa utafiti unajumuisha mahojiano ya sauti, upimaji wa macho kwa kutumia chati, na uchunguzi utafanywa kutumia kamera ya macho kwa sehemu ya mbele. Macho yatapanuliwa na matone ya tropicamide na fundoscopy itafanywa. Hii itafuatiwa na swabs za kiunganishi ambazo zitakusanywa kwa upimaji wa PCR baada ya kuingiza dawa ya ganzi ya macho. Hakuna hatari kubwa mbali na kuongezeka kwa unyeti wa nuru na ukungu wa maono kwa masaa 3-4 yanayosababishwa na tropicamide.

Kushiriki katika utafiti huu ni kwa hiari bila vitisho wala vishawishi vya kifedha au nyenzo vinavyo tarajiwa. Ugonjwa wowote wa macho unaogunduliwa utasimamiwa ipasavyo na kesi yoyote inayohitaji matibabu maalum ya macho itatumwa kwa kliniki ya macho ya KNH kwa usimamizi zaidi. Matokeo ya tuhuma yatapigwa picha kwa kutumia kamera ya simu. Usiri wa kumbukumbu utahifadhiwa.

12.32 Consenting form

I, ...…… of P.O Box .....and telephone number ……. having read the contents of the consent do hereby agree to take part in this study.

Date:..... Signature.....(Participant)

I confirm that I, Dr. Nadya Mustafa, telephone number +254721461106 have explained the nature of my study and examination procedure to the above-mentioned participant.

Date:.....Signature.....(investigator)

Mimi……..sanduku la posta… ..... na nambari ya simu…….. baada ya kusoma yaliyomo kwenye idhini hii nakubaliana kushiriki katika utafiti huu.

Tarehe:..... Sahihi.....(Mshiriki)

Nathibitisha kua mimi, daktari Nadya Mustafa, mwenye nambari ya simu +254721461106 nimemueleza hulka ya utafiti wangu wa kusoma na uchunguzi kwa mshiriki aliyetajwa hapo juu.

Tarehe:.....Sahihi.....(Mchunguzi)

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12.4 Ethical Approval Certificate

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Ref: KNH-ERC/A/343

30th September, 2021

Dr. Nadya Omar Mustafa
Reg. No.H58/34810/2019
Dept. of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 30 SEP 2021 KNH/UoN-ERC P.O. Box 20723 - 00202 NAIROBI

Dear Dr. Mustafa

RESEARCH PROPOSAL: PATTERN OF OCULAR MANIFESTATIONS AND CONJUCTIVAL SWAB POSITIVITY IN PATIENTS WITH CORONAVIRUS DISEASE-19 AT KENYATTA NATIONAL HOSPITAL IN KENYA (P657/08/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 30th September 2021 – 29th September 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. 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.
iv. 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.
v. Clearance for export of biological specimens must be obtained from KNH- UoNERC for each batch of shipment.
vi. 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).
vii. 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.

Protect to discover

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
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The Chair, Dept. of Ophthalmology, UoN
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Prof. Jefitha Karimurio, Dept.of Ophthalmology, UoN

12.5 Approval for Technical Support

MINISTRY OF HEALTH
OFFICE OF THE DIRECTOR GENERAL

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When replying please quote
REF: MOH/DLS/DGH / VOL.II /3882

2nd November, 2021

Nadya Mustafa
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RE: APPROVAL OF A REQUEST FOR TECHNICAL SUPPORT TO FACILITATE A COVID-19 MSC THESIS RESEARCH PROJECT AT THE NATIONAL PUBLIC HEALTH LABORATORIES (NPHL)

The Ministry is in receipt of your request for support to conduct COVID-19 research study leading to an award in MSc in Ophthalmology from the University of Nairobi. This request is detailed in your letter dated 4th October 2021. Your letter indicates that you intend to assess COVID-19 pathologies among hospitalized patients with a view to determining whether the ocular swabs can be used as alternative sources of clinical samples for diagnosis of the disease and if so, what other ocular symptoms are associated with COVID-19 infections. Your application further indicates that you need support to analyze 75 positive samples through the Ministry testing sites such as the National Public Health Laboratories (NPHL). It is however clear that you will cater for your sample collection and patient recruitment. The Ministry also notes that you already have an ethical clearance certificate for the proposed study from Kenyatta National Hospital and the University of Nairobi Ethical review board.

The purpose of this letter is to inform you that your application has been reviewed and recommended for approval. The Ministry is of the opinion that this study has a potential to shed more light on pathobiology of COVID-19 and could therefore contribute to the development of alternative empiric diagnostic strategies for this disease.

You are further directed to get in touch with Dr. John Kiiru, Head Department of Laboratory Services (kyirow@gmail.com) to discuss further on modalities of testing of the 75 samples at the NPHL and in order to assess compatibility of your study protocol with the NPHL COVID-19

testing algorithm. Please ensure that the study fully adheres to ethical practices of research that include humane treatment of patients, ensuring that the rights of patients to study participation are safeguarded. Also, ensure that patient's data is protected from any form of breach and from any direct or indirect loss of confidentiality. The Ministry is looking forward to receiving the final report on the findings of your study.

Dr. Patrick Amoth, EBS
Ag. DIRECTOR GENERAL FOR HEALTH

Copy to:

Ag. Head, Directorate of Public Health

Head, Department of Laboratory Services