EFFECTIVENESS OF FASCIA ILIACA COMPARTMENT BLOCK FOR POST-OPERATIVE ANALGESIA FOLLOWING HIP SURGERY AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

BY

NELLY MONG'INA MAOGA

A THESIS SUBMITTED IN PARTIAL FULFILMENT FOR THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN ORTHOPEDIC SURGERY OF MOI UNIVERSITY.

DECLARATION

Declaration by Candidate:

This thesis is my original work and has not been presented for a degree in any other university. No part of this thesis may be reproduced without prior written permission of the author and or Moi University.

Signature:…….. Date:……..

SM/PGORT/01/2015

Declaration by Supervisors

This thesis has been submitted for examination with our approval as Moi University Supervisors.

Dr. Wangari Siika

(MBChB, MMED (Aneas), FRCA)

Consultant Anesthesiologist

Signature:…….. Date:……..

Dr. K Lelei

Consultant Orthopedic Surgeon

Senior Lecturer in Orthopedics Department

School of Medicine, Moi University

Signature:…….. Date:……..

ACKNOWLEDGEMENT

I thank the almighty God for the gift of life.

I cannot express enough thanks to my supervisors; Dr. W. Siika and Dr. K. Lelei for their support and encouragement.

My sincere appreciation goes to the Orthopaedic and Rehabilitation Department of Moi University for the Learning Opportunity they have offered me.

I thank the Kenyan Government for the grant offered for this study through the National Research Fund.

Finally, to my caring and loving parents and siblings, my deepest gratitude for their endless encouragement when times got rough.

EFFECTIVENESS OF FASCIA ILIACA COMPARTMENT BLOCK FOR POST-OPERATIVE ANALGESIA FOLLOWING HIP SURGERY AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

ABSTRACT

Background: Pain following hip surgery causes significant patient discomfort. In addition to other analgesic options, the use of regional blocks offer localized and long-term pain relief. Fascia iliaca compartment block (FICB) is one such regional block that has been shown to be successful in pain control following hip surgery. There is minimal use of this block at Moi Teaching and Referral Hospital (MRTH). The aim of this study was to assess the effectiveness of FICB for analgesia when performed by an orthopedic resident following hip surgery.

Objective: To assess the effectiveness of FICB as part of multimodal analgesia for postoperative analgesia following hip surgery at MTRH.

Methods: A randomized control trial was carried out from 1st July 2017 to 30th March 2019 at MTRH. Seventy adult patients who met the inclusion criteria for FICB were enrolled in the study after obtaining an informed consent. Thirty-five patients were randomized into Group A and received FICB and the other 35 patients who were randomized into Group B did not receive FICB. The FICB was administered by a trained orthopedic resident, using the 'two pop' technique, in the post-anesthetic care unit. The standard dose of 0.35ml/kg of 0.5% bupivacaine was used for the block. Pain was assessed using the Numerical Rating Scale at 2, 4, 6 and 8 hours after surgery with the limb in anatomical position and at 15^0 flexion. The data collectors were blinded. A failed FICB block was defined as less than 3-point drop in NRS and normal sensation to cold metallic object on examination. All patients received intravenous morphine and paracetamol at a dose of 0.1mg/kg and 15mg/kg respectively and intramuscular diclofenac at a dose of 3mg/kg for postoperative analgesia. Data were analyzed using STATA version 13. T-test was used to compare the mean pain scores between the two groups.

Results: At anatomical position, the mean pain scores at 2, 4 and 6 hours for group A were 4.5(±1.9), 2.7 (±2.1) and 3.9 (±1.5), while for group B were 8.4 (±0.8), 7.1(±1.1) and 6.0 (±1.6) ($p<0.001$). With the limb at 15^0 flexion, the mean pain scores at 2, 4 and 6 hours for group A were 5.5 (±1.5), 3.2(±2.9) and 4.0 (±2.0) while for group B were 9.2 (±0.6), 8.4 (±1.0) and 7.1(±1.2) ($p<0.001$). There was no statistical significant difference in pain scores between the groups at 8 hours with patients limbs in anatomical position ($p=0.659$) and with the patients limbs in 15^0 flexion ($p=0.46$). The failure rate for FICB was 17.1% (n=6).

Conclusion: Facia iliaca compartment block offered effective analgesia for the first six hours following hip surgery. The failure rate of FICB was low at 17.1%.

Recommendation: Fascia iliaca compartment block be adopted into the multimodal analgesia following hip surgery at MTRH. Further studies looking at longer acting analgesic options be conducted.

ABBREVIATIONS/ACRONYMS

ASA	American Society of Anesthesiology
EMS-nurses	Emergency Service Nurse
FICB	Fascia Iliaca Compartment Block
Kg	Kilograms
Mg	Milligrams
mg/kg	Milligrams/ kilogram
mls	Millilitres
MTRH	Moi Teaching and Referral Hospital
NOFERP	Neck of Femur Enhanced Recovery Program
NRS	Numerical Rating Scale
PCIA	Patient Controlled Intravenous Analgesia
VAS	Visual Analogue Sacle
W.H.O	World Health Organization

DEFINATION OF TERMS

Hip Surgery: Operations following proximal femur fracture (hip fracture)..

Resident: Medical Postgraduate Student

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE: INTRODUCTION

1.1 Background

Pain, according to the World Health Organization's (WHO) definition, is "an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in terms of such damage". It is a presenting complaint in trauma patients and its relief is a core medical ethic (Brennan, Carr, & Cousins, 2007).

Termed as the 'hidden epidemic' by W.H.O, trauma is a common cause of fractures. A hip fracture is a break of the bone in the proximal femur. Fractures are common in trauma patients, especially in the elderly. Fractures are painful and appropriate analgesia is an important objective to an orthopedic surgeon. The principle management is surgery.

In orthopedics, pain is managed via a multimodal analgesia. In multimodal analgesia, two or three analgesics that act at different levels of the pain pathways are administered concurrently. This aids in achieving a maximum effect of analgesia.

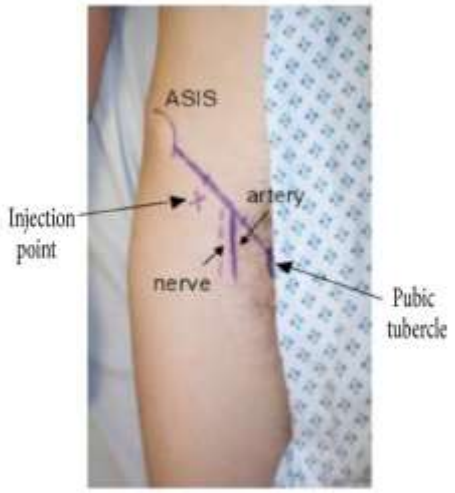


Figure 1: Landmark for FICB (Range & Egeler, 2010)

First described in *Dalens et al.,* in 1989, Fascia Iliaca Compartment Block (FICB) is a simple, inexpensive regional block administered either pre or post-operatively for analgesia of hip fractures and hip surgery respectively. It is also indicated for analgesia following above knee amputation, knee surgery in combination with sciatic block, plaster application for femoral bone fracture

in children and lower leg tourniquet pain during awake surgery.

Fascia Iliaca Compartment Block is administered using the landmark/ ‘two pop’ technique or with the aid of an ultrasound. . *Dalens et al*., (1989) described it using the landmark technique that is also referred to as the ‘two pop’ technique.

In the ‘two pop’ technique, a long acting local anesthesia is administered using a blunted or a short-beveled needle insert at a point 1cm caudal from the lateral and middle third of a line drawn from the anterior superior iliac spine and the pubic tubercle. An ultrasound may also be used to guide in the administration of the drug.

Anatomically, a needle inserted at this point penetrates the skin, adipose tissue, superficial fascia, the fascia lata, fascia iliaca and ends up in the fascia iliaca compartment. Once in the compartment, local anesthesia is infiltrated and it blocks the femoral nerve and the lateral cutaneous nerve of the thigh (Range & Egeler, 2010). In one third of the case it may block the obturator nerve by spreading in between the psoas and iliacus muscle.

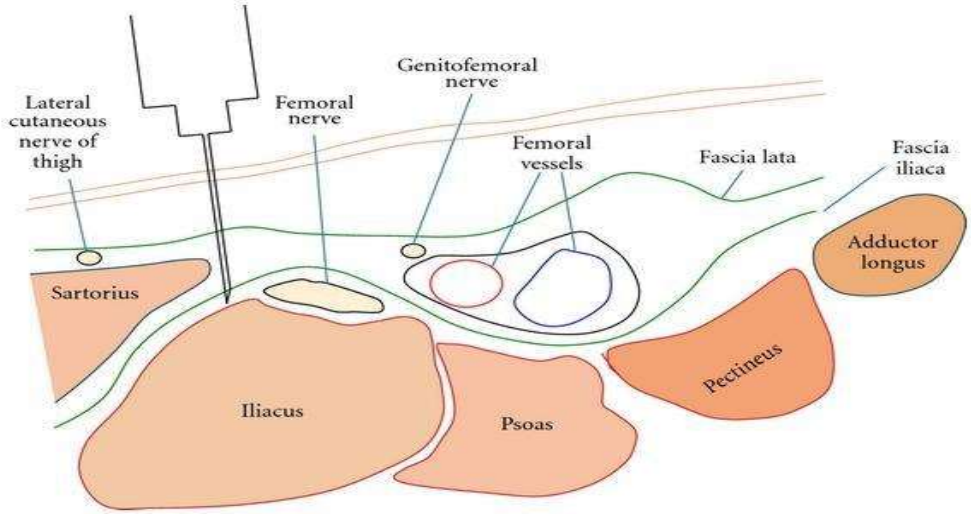


Figure 2: Fascia Iliaca Compartment Space (Range & Egeler, 2010)

This block is part of pain therapy, both pre and post operatively. It is easy to perform and its treatment is administered by emergency nurses, emergency doctors and paramedics.

Fascia iliaca compartment block can be given either as a single shot or as a continuous infusion. In continuous infusion a needle is inserted as above and a catheter is threaded through the needle into the fascia iliaca space. Local anaesthesia is then injected through the catheter. This can be maintained for several days.

Complications of FICB include hematoma, intravascular injection, local anaesthetic toxicity, temporary or permanent nerve damage, infection and block failure. These complications are minimized by sound knowledge and good training of the clinician.

1.2 Problem Statement

Pain is an important public health concern and relief from it is a basic human right (Fishman, 2007). However, the International Association for the Study of Pain claim that acute pain is not adequately managed in 50% of patients with trauma and patients who have undergone surgery (Ballantyre, 2011).

Globally the prevalence of post-operative pain ranges from 50-75% (Phillip, Kuo, & Schroeder, 2007). In a tertiary hospital in Moshi, Tanzania, post-operative pain prevalence ranges from 77.4%-85.5% (Masigati, 2014).

In Kenya, a study done at Aga Khan University Hospital Nairobi, revealed a post-operative pain prevalence of 55.3% in the first 24 hours among patients who had undergone a day case surgery (Mwaka, Thikra, & Mung'ayi, 2013).

At Moi Teaching and Referral Hospital, a research done on the prevalence and correlates of pain and pain treatment, revealed that 66% of hospitalized patients were not adequately treated for pain (Huang, et al., 2013).

Severe postoperative pain is often observed among orthopedic patients (Ekstein & Weinbroum, 2011) and pain management in patients who have undergone hip surgery is not only difficult but challenging (Waldam, 2017).

Ill managed postoperative pain increases myocardial oxygen demand, decreases vascular perfusion and suppresses immunity. It also leads to prolonged immobility which predisposes the patient to an increased risk post-operative complications such as deep venous thrombosis, pneumonia and poor wound healing (Carr & Goudas, 1999) (Breivik, 1998). Acute pain not managed adequately increase the risk of developing chronic pain (Sinatra, 2010)

Opioids are the ideal analgesics for moderate to severe pain, however, opioids are administered with caution due to their side effects. Furthermore, there is a short supply of opioids in the developing countries (Manjiani, Paul, Kunnumpurarth, Kaye, & Vadivelu, 2014)

1.3 Justification

Relief from pain is vital. As Albert Schweitzer, a surgeon and a 1952 Noble Peace Prize winner once said; “We must all die. But that I can save him from days of torture that is what I feel as my great and ever new privilege. Pain is a more terrible lord of mankind than even death itself.”

Inadequately treated pain is not only viewed as poor medical practice, but it is unethical and considered as a violation of human right (Brennan, Carr, & Cousins,

2007). Effective postoperative pain management not only improves patient satisfaction and comfort, but increases patient recovery, reduces chances of developing deep venous thrombosis and chronic pain.

Fascia iliaca compartment block have been proven to aid in postoperative pain management for patients who are undergoing hip surgery (Denzi, Atim, Kurklu, Cayci, & Kurt, 2014). Studies have also revealed that patients who receive FICB as an analgesic consume less opioids and in comparison to those who do not receive FICB. This finding is an added advantage of FICB as patients have reduce exposure to the side effects of opioids (Hanna, Gulati, & Graham, 2014).

Once an anesthesia domain, FICB is an easy to perform regional block that is currently administered by orthopedic residents, emergency nurses and paramedic as an analgesic patients with hip fractures (Dochez, et al., 2014).

Fascia iliaca compartment block is a fast acting block that has been incorporated into the multimodal analgesia for a hip surgery. The two pop technique, intended for the study, is an inexpensive procedure that would aid in pain treatment for patients. This study would not only educate but also aid current Orthopaedic clinicians on new modalities of an easy quick pain relief.

1.4 Research Question

How effective is the FICB as part of multimodal analgesia when performed by an orthopedic resident for postoperative pain treatment following hip surgery at Moi teaching and Referral Hospital (MTRH)?

1.5 Objectives

1.5.1 General Objective

To assess the effectiveness of fascia iliaca compartment block as part of multimodal analgesia when performed by an Orthopaedic resident for postoperative pain treatment following hip surgery at MTRH.

1.5.2 Specific Objectives

(i) To determine differences in postoperative pain intensity, using the numerical rating scale, when the limb is in anatomical position among post-hip surgery patients who received FICB and systemic analgesia versus systemic analgesia alone at MTRH.

(ii) To determine differences in postoperative pain intensity, using the numerical rating scale, when the limb is flexed at 150 degrees among post-hip surgery patients who received FICB and systemic analgesia versus systemic analgesia alone at MTRH.

(iii)To assess the failure rate among post-hip surgery patients who received fascia iliaca compartment block at MTRH.

CHAPTER TWO: LITERATURE REVIEW

2.1 Fascia Iliaca Compartment Block

Frist performed in 1989, fascia iliaca compartment block was shown to be an effective analgesia for post-operative pain management in pediatric patients who had undergone femur surgery (Dalens, Venneuville, & Tanguy, 1989).

Local anesthesia is administered into the fascia iliaca compartment. This is a potential space that is bounded:

- Anteriorly by the posterior surface of fascia iliaca
- Posteriorly by the anterior surface iliacus muscle and psoas major
- Medially the vertebral column
- Cranial laterally the inner lip of the iliaca crest
- Craniomedially it continues with the space between quadratus lumborum muscle and its fascia.

Fascia Iliaca Compartment Block is administered with the patient is supine position and the person performing the block standing on the side of the limb where the block is to be administered. Landmarks are identified by the bony prominence of the anterior superior iliac spine and pubic tubercle. A line is drawn from these two points and divided into thirds. At the junction between of the outer one third and the inner two thirds and 1cm distal to the intersection is the insertion point. The femoral pulse is palpated for and should be felt 1.5 to 2 cm medial from the insertion point. This ensures a safe distance from the femoral vein, artery and nerve. This also hinders femoral nerve impalement and administration of the drug into the vessel. The area is cleaned with an anti-septic and a 22 gauge short beveled needle is inserted at 60^0 and once through the skin the angle is reduced to 30^0 and the needle is advanced a further

1-2 mm. The sagittal plane is maintained throughout the course of the needle insertion in order to avoid injury to the vessels medially. Two ‘pops’ of the fasciae are felt for. The first ‘pop’ is when the needle penetrates the fascia lata and the second ‘pop’ signifies penetration of the fascia iliaca. Once in the fascia iliaca compartment, aspiration is done to make sure that the needle is not in the femoral vessels. The drug is injected slowly with no resistance. If there is resistance, it indicates that the needle is within the iliacus muscle and a slight withdrawal of the needle will ensure one is in the fascia iliaca compartment. With ultrasound guided FICB, the aim is to visualize the iliacus fascia and the femoral nerve and inject the anesthesia below the iliacus fascia. Drugs used for the procedure are long acting local anaesthetics such as 0.25%-0.5% bupivacaine, 0.25-0.375% levobupivacaine or 0.25%-0.5% ropivacaine. These drugs produce anesthesia by inhibiting conduction at the nerve endings. Doses are calculated at 0.35ml/kg.

A comparative study conducted in France (Dalens, Venneuville, & Tanguy, 1989) between FICB and femoral 3 in 1 block established FICB was an effective analgesic. One hundred and twenty pediatric patients aged between 0.7 to 17 years were recruited into the study after an informed consent. After randomization, 60 children were allocated into the FICB group while 60 received a femoral 3 in 1 block after the surgery for analgesia. The landmark technique (“two pop” techniques) was used in this study. The 3 in 1 femoral nerve block was administered with the aid of a nerve stimulator. Local anesthetic used was a mixture 1% lidocaine and 0.5% bupivacaine. FICB was conducted by the same anesthetist in the induction room in the theater. A block was counted as successful when there was no pain elicited upon pinching of the lateral, medial and anterior aspects of the thigh block. FICB was counted a failed if there was a motor response to the pain following pinching or when the child

complained of pain. Analgesia was found to be better in pediatrics patients who had received a FICB as compared to those who had received a 3 in 1 femoral block, at a rate of 90% and 20% respectively. The FICB and 3 in 1 femoral nerve blocks were performed by one anesthetist to avoid inter-person variability. In the author's view, FICB was easier to perform and had fewer complications compared to the 3 in 1 femoral nerve block. The technique required neither unusual skills nor expensive devices and did not threaten any vital organs. FICB was recommended as a postoperative analgesic in pediatric patients who hand undergone femur surgery.

In 2003, a study was done in France (Lopez, 2003) to investigate whether FICB significantly reduced the requirement for systemic opioids. The "two pop" techniques was used and the block was administered by the attending emergency physician at the Accident and Emergency to patients diagnosed with proximal femur fracture. Fascia Iliaca Compartment Block was found to be an effective analgesic that reduced morphine consumption in pre-operative patients.

In America (Monzon & Iserson, 2007), prospective interventional uncontrolled was conducted to test the efficacy and feasibility of fascia iliaca compartment block when administered by emergency physicians. Adequate analgesia was important as it decreased the risk of delirium in the elderly patients. Adequately treated pain also made it convenient for the attending physician to take a detailed history and perform a satisfactory physical exam. A total of 63 patients all with proximal femur fracture were enrolled sequentially after an informed consent. The fascia iliaca compartment block was administered using the landmark technique with a 21 gauge needle and 0.3ml/kg of 0.25% bupivacaine was infiltrated fascia iliaca compartment. The 10 visual analog scale (VAS) was used to assess for pain intensity at 15 minutes, 2 hours and 8 hours after FICB administration. Other variables assessed included the heart

rate, mean arterial pressure and respiratory rate. In the event that there was no change in pain level or comfort of the patient, the block was regarded as a failure. Results revealed a significant decrease in pain scores at 15 minutes and 8 hours, respectively ($p<0.05$). The heart rate, mean arterial pressure and respiratory rate all decreased throughout the 8 hour period. The author found that emergency physicians learnt the technique quickly and that fascia iliaca compartment block could be performed easily using the emergency equipment.

A prospective observational study was carried out in Denmark (Hogh, Dremstrup, & Jensen, 2008). The main aim was to investigate the efficacy of FICB when performed by junior registrars. The block was given as supplement analgesia for preoperative pain. The landmark technique was to administer the FICB block. . The drugs used were 30 ml bupivacaine (2.5mg/ml) and 10 ml of lidocaine (2%). The amount was halved in patients less than 50kgs. A total of 187 patients were recruited. A 5 step verbal pain score and maximum hip flexion were used to access the efficacy of FICB both subjectively and objectively. Pain intensity was assessed at 15 minutes and at 60 minutes post administration of the block. The same time frames were used to assess pain intensity with the limb in maximum hip flexion. The median pain scores were 2.2 (SD=0.92) before administration of the block, and this decreased to 1.5 (SD=0.78) and 1.2 (SD=0.78) at 15 minutes ($p<0.001$) and 60 minutes ($P=0.021$) respectively. Pain free hip flexion increased from a median of 15 degrees (SD=17) pre block to 28 degrees (SD=21) at 15 minutes post block ($p=0.014$) and at 60 minutes pain free hip flexion was at 37 degrees (SD=36, $p=0.030$). Using hip flexion measurements, FICB was found to be effective in 69.5% (CI 0.56-0.81) for the patients. A difference of 10 degrees in hip flexion was regarded as significant in the two groups. With no complications reported during the study period, the authors concluded that FICB was

feasible by junior registrars and an efficient pre-operative analgesic supplement. It required inexpensive equipment with minimal risk approach and easy to perform.

A randomized double blinded clinical trial was carried out in the United State (Stevens, Harrison, & McGrail, Dec 2007). The researcher set to find out if a modified FICB had a morphine sparing effect. Forty four patients were enrolled post-operatively following a unilateral total hip arthroplasty. The trial group received a block, whereas the control received a placebo of normal saline. The amount of morphine consumed was compared between the two groups at 3, 6, 12 and 24 hours post operatively. The trial group consumed less morphine compared to the control with a mean difference of 15.5mg of morphine at 24 hours post operatively. The modified fascia iliaca block was concluded to have a significant morphine sparing effect ($p<0.001$). A modified FICB is also known as a continuous FICB. In a modified FICB, a catheter is inserted into the Fascia iliaca compartment and analgesia is administered through the catheter. Modified fascia iliaca compartment allows a longer duration of analgesia. .

A prospective observational study was carried out in Spain (Arrola, Telletxea, Bourio, Maguregui, & Larracoechea, 2009) to assess the efficacy of FICB as a post-operative analgesia. Forty one were enrolled into the study divided into an intervention arm, receiving an FICB, and a control arm that received systemic analgesia. Pain intensity was accessed using a VAS immediately after surgery and 24 hours later. The intervention arm had a lower pain score for the first 24 hours ($p<0.001$) but there was not a significant difference in pain score at 24 hours post operatively ($p=0.57$). It was concluded that a single shot of FICB was an effective analgesic for postoperative pain treatment during the first few hours in the ward, but not the entire 24 hours.

A prospective, nonconsecutive interventional case series study was performed to investigate the efficacy and feasibility of FICB when performed by emergency physicians in England (Elkhodair, Mortazavi, Chester, & Pereira, January 2011). Emergency physicians attended a 2 hour training session that covered the relevant knowledge on administration of FICB. Fascia iliaca compartment block was administered using the landmark. Local anesthesia used were 30mls 1% lignocaine and 0.5% bupivacaine or levo-bupivacaine administered in age adjusted doses. Pain intensity was VAS. A failed FICB was defined as a no reduction in pain score by 3 points or less from the base line. Pain scores were taken at in 30 minutes and 60 minutes after administration of FICB. It was noted that there was a total mean reduction of 5.1 ($p<0.001$) in the pain score. The success rate of FICB was 77.4%. It was concluded that FICB was a safe and effective analgesic and could be administered by emergency physicians.

In James Paget University Hospital, in England, have an informal training program that teaches emergency physicians to administer FICB. The training was introduced with the sole aim of improving pain treatment among patients with hip fracture. (Leeper, Bradon, Morgan, Cutts, & Cohen, 2012).

A randomised control trial done in Japan (Fujihara, et al., 2013) assessed the effectiveness of FICB as an analgesic for patients who had sustained a hip fracture as well patients who had undergone hip surgery. The study was carried out over a period of 7 months and total of 56 patients were enrolled. The patients were randomized into two arms: an intervention arm that received FICB and a control arm that received analgesics as per the hospital protocol. Pain intensity was assessed both subjectively using the VAS and objectively when the limb was flexed to 15 degrees. FICB was administered by an orthopedic resident using the landmark technique.

Local anesthesia used was 10mls 0.75% of ropivacaine along with 10mls of 0.2% mepivacaine. Pre-operative pain score were evaluated at 10 minutes and 12 hours after FICB administration. Post-operative pain score were assessed at 6 hours and 12 hours after FICB administration. A statistical significant analgesic effect was observed in the intervention arm compared to the control arm. Pain score reduced by a mean of 31±18.2 vs. 92±6.3 ($p<0.05$) at and 36±19.0 vs. 81±7.8 ($p<0.05$) at 12 hours in the intervention arm when compared to the control arm respectively. The researcher noted a marked improvement postoperative pain treatment in the intervention arm compared to the control arm with mean pain scores of 22±10.7 vs. 49±17.6 at 6 hours ($p<0.05$) and 31±14.1 vs. 59±17.1 at 12 hours ($p<0.05$). No complication or FICB failure was reported. The researcher concluded that FICB was an easy technique to learn and offered excellent pain relief.

A literature review was conducted in 2014 (Chesters & Atkinson, 2014) to deteremine the efficacy of FICB as an analgesic for proximal femur fracture. Literature search was done on EMBASE, PubMed, and CINAHL and Google scholar. A total of 14 articles were reviewed after meeting the methodological quality criteria. The literature review reviled that FICB had a pivitol role as a first line analgesic for proximal femur fracture.

A randomized control trial done in Turkey (Denzi, Atim, Kurklu, Cayci, & Kurt, 2014) compare postoperative analgesic efficacy of FICB versus Femoral 3 in 1 block versus standard analgesia. A total of 70 patients, aged between 20-80 years, were recruited into the study. Study parameters included pain intensity over 24 hours, cortisol hormone levels and adrenocorticotropic hormone levels. Pain is a significant stressor both the psychologically and physiologically. The physiological responds to stress is the release adrenocorticotropic and cortisol hormone. Reduction in the levels

of hormones indicated adequate postoperative pain treatment. All patients were administered the block in the operating room 30 minutes before surgery. Femoral 3 in 1 block was administered with the aid of a nerve stimulator, and FICB was administered with the aid of an ultrasound. Pain intensity was assessed using a VAS over a 24 hour period. Blood was drawn to check cortisol hormone levels and adrenocorticotropic hormone. Pain management was better in patients who received FICB, followed by patients who received a femoral 3 in 1 block while the control group had the worst pain scores. The authors concluded that femoral 3 in 1 block and FICB should be included as part of multimodal analgesia in an aim to improve post-operative pain management.

In 2014, over a period of 8 months in Ethiopia, a case control study was carried out (Kumie, Gebremedhn, & Tawuye, 2015). The authors sought to find out if FICB was an efficacious analgesic for postoperative pain treatment following femur surgery. A total of 40 patients were enrolled into the study were grouped into an intervention arm that received FICB and systemic analgesia and a control arm that received systemic analgesia only. An anesthesiologist administered FICB using the landmark technique. A weight adjusted dose of 0.25% bupivacaine was used. Pain intensity was assessed using the 100mm VAS at 15minutes, 2,6,12 and 24 hours post FICB administration. Other variables measured included total analgesia consumption and time of first request for analgesia. The study revealed a significant difference in the total amount of diclofenac analgesia consumed over a period 24 hours between the intervention arm and control arm (FICB 75 vs. control 100 $p=0.001$).Time for first request for analgesia was prolonged in the intervention arm in comparison to the control ($p<0.05$). The authors concluded that pain treatment was better in the intervention arm in comparison to the control arm.

A study was done in China (Nie, et al., 2015) to evaluate the efficacy of continuous FICB for postoperative analgesia after hip fracture surgery. Eighty eight patients were enrolled into the study and randomized into two groups: Fascia iliac Compartment Block group (FIB) and Patient Controlled Intravenous Analgesia (PCIA) group. Postoperative pain was assessed using the numerical rating scale (NRS) 2, 4, 6, 8, 12, and 24 hours after analgesia was started. The landmark technique was used to administer continuous FICB over a duration of 12 hours. Local anesthesia used in the study was Ropivacaine. Patients in the FIB group reported less pain than those in the PCIA group (RM~ANOVA p=0.039; 95% CI -1.10 to -0.03).

A randomized control trail carried out in Belgium (Desmet, et al., 2017) found a statistical significant reduction in pain scores and morphine consumption among patients who received FICB as an analgesic following total hip surgery. Fascia iliaca compartment bock was administered with the guide of ultrasound. Patients were randomized into an FICB group and a control group. In the FICB group patients received the FICB while in the control group received systemic analgesia. The FICB group had lower mean pain score at 1, 2, 4 and 24 hours postoperatively (p=0.0012, p=0.0051 and p=0.0357) in comparison to the control group. There was no statistically significant reduction in pain scores at 6, 12 and 48 hours. This was attributed to the fact that patients had PCIA and thus pain score reduced with time.

A meta-analytical (Yang, Li, Chen, Shen, & Bu, 2017) study was conducted to evaluate the efficacy and safety of FICB as an analgesia for postoperative pain following lower limb surgery. The authors carried out a literature search through PubMed, EMBASE and Cochrane Library. The results revealed that patients who received FICB had lower pain score at 4 hours (mean difference [MD] = -1.17; 95% CI= -2.30 to -0.05; p=0.041), 12 hours (MD= -0.41; 95% CI= -0.76 to -0.05; p=0.026)

and 24 hours (MD= -2.06; 95% CI=-3.82 TO -0.30; p=0.022). The conclusion was concluded that FICB is an effective and safe method to alleviate pain following lower limb surgery.

In United States (Shariat, et al., 2013), a randomised contol trial was carried to assess the efficacy of FICB as a postoperative analgesia following hip surgery. A total of 32 patients were randomized into two groups: a FICB group and a Sham Group. The FICB group received the block while the Sham group received systemic analgesia. The FICB was administered with the guide of an ultrasound. Local anesthetic used was 0.5% ropivacaine. Patients in the FICB group had similar pain scores to patients in the Sham group. The possible explanation for the lack of efficacy of FICB in this study was the technical aspect and pharmacological dose that may have been inadequate for analgesia.

A study done in Korea (Bang, Chung, Jaejung, Bak, & Kim, 2016) to evaluate the efficacy of FICB as postoperative analgesia found no statistical significance reduction in pain in score. A total of 22 patients were randomized into two groups following hip surgery. Fascia iliaca compartment blocks were administered with the aid of an ultrasound. The local anesthesia used was 0.2% ropivacaine. The VAS score used to assess pain intensity at 4, 8, 12 and 24 hours postoperatively. The VAS scores were similar in both groups. This was attributed to the fact that any patient in their study who reported a pain score of greater that 4 was given additional analgesic dose of 25mg of tramadol.

2.2 Pathophysiology of Pain

Pain following hip surgery is caused by the incision and manipulation of the periosteum and soft tissues. Innervation around the hip is by femoral nerve, obturator and the lateral femoral cutaneous nerve of the thigh.

According to the “labeled wire principle” each nerve point ends at certain points in the brain. Thus, after hip surgery, free nerve endings (nociceptors) that are the chief receptor of pain, are stimulated. This stimulus is in turn transmitted from the joint via periphery afferent nerve axons to the spinal cord.

The cell body of the neuron is located in the dorsal root ganglion. At the cell body two processes are sent, one to the peripheral muscle and the second to the spinal cord.

Once in the spinal cord, the axons relay the stimulus on to second order neurons. Some decussate in the spinal cord to lie in the anterolateral part of the spinal cord.

The stimulus then ascends through the spinal cord to its target centers, the brain stem and the thalamus, via the spinothalamic tract and reticulothalamic pathway respectively. At the thalamus, pain pathways will terminate at the ventrocaudal and medial.

From the ventrocaudal, neurons project directly to the somatosensory cortex of the frontal lobe and those from the medial project to many areas in the forebrain including the somatosensory (Fong & Schug, 2014).

2.3 Analgesia in Orthopedics

2.3.1: Pharmacological Analgesia in Orthopedics

Multimodal analgesia is used in patients with hip fractures so at optimize analgesia. This is needed in acute postoperative pain management so as to improve pain management. Opioids, non-steroidal anti-inflammatory drugs and acetaminophen are the drugs most commonly used in two or three combinations. Nerve blocks are also used for analgesia (Range & Egeler, 2010).

Regional nerve block is an anesthesia in which part of that body is anesthetized or "made numb". It has been traced back to the South Americans who first knew the numbing properties of cocaine. It was then, in the 1800 that Europe learnt of local anesthesia. Before this, an ice bag or pressure applied to the skin overlying the peripheral nerve reduced pain (Mulroy, 2014).

In Africa, history shows that analgesia was achieved by using herbs and plants. Although medical knowledge was passed down from one generation to the next via verbal communication, there was an attempt to anaesthetize the patient in one form or another during surgical procedures.

In Nigeria, Tabermontana crassa is an herb that is used by traditional bonesetters, practitioners in joint manipulation. The herb is used as a local anesthetic. It is boiled and the steam is applied over the joint before the procedure and the leaves are placed over the affected joint after 30 minutes (Kinyungu, 2010).

Regional anesthesia has been associated with an improved dynamic pain relief. Fascia iliaca compartment block is one such regional block. One of the many advantages of regional nerve blocks for hip and femur fractures is that they have been shown to reduce pain and need for intravenous opioids (Ritcey, Pageau, Woo, & Perry, 2016).

2.4 Pharmacology of Drugs used in FICB

Local anesthetics; bupivacaine, levobupivacaine, mepivacaine and lidocaine are all being used in FICB. Local anesthetics produce anesthesia by inhibiting nerve excitation and blocking nerve conduction. The drugs reversibly binds to an inactivated channel. Sodium entry into the nerve cell is necessary for depolarization of nerve cell membrane and subsequent propagation of impulses along the course of the nerve. Individuals lose sensation in the area supplied by the nerve, when the nerve loses depolarization and capacity to propagate an impulse.

These drugs belong to the amine amides. In their chemical structure they all have an intermediate chain of amine on one end and an aromatic ring on another. Different structures in the amine and aromatic end change the chemical activity.

The maximum doses of each drug and duration of action are shown in table 1.

Table 1: Local anesthesia drugs, dosage and duration of action.

Drug	Maximum dose (with epinephrine)	Duration (with epinephrine)
Bupivacaine	2.5 mg/kg (3mg/kg)	4 hours (8 hours)
Mepivacaine	5 mg/kg (7mg/kg)	3 hours (6 hours)
Levobupivacaine	2.0 mg/kg or 400mg/kg in 24 hours	4-6 hours (8-12 hours)
Ropivacainen	2 mg/kg	3 hours (6 hours)

Epinephrine in local anesthetics aids in increasing the duration of action of the drug by delaying the absorption of local anesthetics at the injection site. Epinephrine also helps in vasoconstriction as local anesthetics are vasodilators (Becker & Reed, 2012).

2.5 Pain Scales used for Pain Scores

Pain scales are valuable tools for clinicians to assess pain intensity and guide pain treatment. They include single item scale and continuous rating scales. The Numerical Rating Scale is an eleven point scale that is used worldwide. This scale has also been used in MTRH and is a validated tool. The patients are asked on scale of 0 to 10 to rate the intensity of pain they have felt. It is interpreted as follows:

- 0 is no pain.
- 1-3 is mild pain
- 4-6 is moderate pain
- 7-10 is severe pain

This is also a validated tool in our setup (Huang, et al., 2013).

Pain scales are tools that give a subjective score of pain intensity. The effectiveness of FICB is assessed subjectively with the limb at rest (Hogh, Dremstrup, & Jensen, 2008) and an objective assessment is done with the limb at 15 degrees flexion (Foss, Kristensen, Bundgaurd, Bak, & Herring, 2007).

CHAPTER THREE: METHODOLOGY

3.1 Study Site

The study was carried out at Moi Teaching and Referral Hospital (MTRH) in Eldoret, Kenya. Located in Uasin Gishu County, it is the second largest referral hospital in Kenya.

Serving a population of up to 20 million people, it covers the Western part of Kenya and Eastern Uganda. It has a bed capacity of 1000 and sees an average of 600 patients on an outpatient basis daily.

According to MTRH records department, the orthopedic department sees a total of 7000 patients a year, of which approximately 2% are patients with hip fractures.

3.2 Study Design

The study was a randomized controlled trial, single blinded, in which the patients were randomized into two groups. One group received a single shot of fascia iliaca compartment block along with systemic analgesia while the other group received systemic analgesia alone. The data collectors were blinded as to the analgesia medications the patients received.

In keeping with the multimodal analgesia therapy used in Orthopaedic practice, the systemic analgesics and their dosage used in this study included:

Opioid: Intravenous morphine 0.1mg/kg/8 hourly (drug batch number: 90KD089)

Non-steroidal anti-inflammatory: Intramuscular diclofenac 75mg/12 hourly (drug batch number: 160805)

Intravenous paracetamol 15mg/kg/8 hourly (drug batch number: DJ60335)

Group A received the systemic analgesia along with FICB and Group B received the systemic analgesia. Bupivacaine 0.5% was the local anesthetic used at a dose of 0.35ml/kg.

The study data that was to be collected would include:

- Social demographic data
- Pain score, using the NRS, before block administration and at 15 minutes after block administration, then at 2, 4, 6 and 8 hours after surgery.
- Pain score, using the NRS scale, with limb at 15^0 flexion before FICB administration and 15 minutes after FICB, then at 2, 4, 6 and 8 hours.
- Classification of hip fracture:

Hip fracture: Fracture neck femur.

Inter-trochanteric fracture.

Sub-trochanteric fracture

- Surgical Approach
- Surgical treatment
- Anesthesia
- American Society of Anesthesiology Classification (ASA)

A successful block was defined as no perception to cold stimuli elicited by a metal touch on the anterior, medial and lateral compartment of the thigh and a drop of 3 points on the pain scale after administration of the block.

This data was collected on closed ended interview administered questionnaire, appendix 2.

3.3 Study Duration

The study was carried out over a period of one year and eight months, from July 2017 to March 2019.

3.4 Study Population

Patients who were scheduled for hip surgery were identified to participate in this study.

3.4.1 Inclusion criteria

The criteria included patients:

Patients 18 years and above with a confirmed radiological diagnosis of a hip fracture.

Patients fit for surgery, according to ASA

3.4.2 Exclusion criteria

The exclusion applied to patients who had the following contraindications for fascia iliaca compartment block. These included:

i. Allergy to the drugs being administered (morphine, paracetamol, diclofenac and bupivacaine)
ii. Infection in the inguinal area
iii. Glasgow coma scale of less than 14
iv. International Normalized Ratio (INR) >1.4
v. Inguinal hernia
vi. Multiple fractures
vii. Contraindication to surgery
viii. Impalpable femoral artery: during administration of FICB, the femoral artery should medial to the point of administration. In the event that femoral artery cannot be palpated, then FICB is not administered as it would pose a risk.

3.4.3 Study Flow Chart

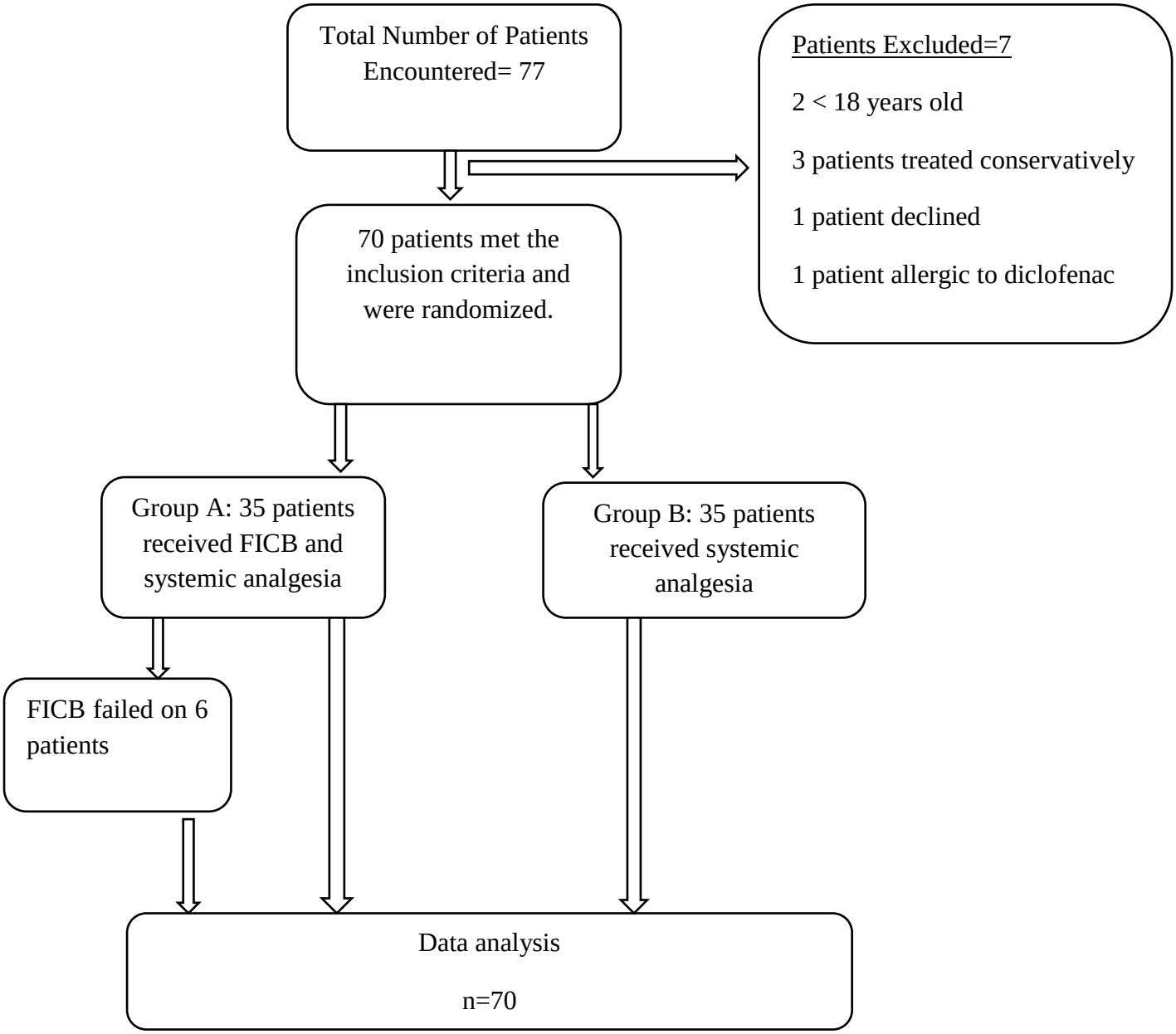


Figure 3: Study Flow Chart

3.5 Sample Size

The aim of the study was to evaluate the effectiveness of FICB as part of multimodal analgesia, when performed by an orthopedic resident, following hip surgery at MTRH.

Studies done comparing the effectiveness of FICB to the standard of care showed a 3 score difference on the VAS scale at 6 or 8 hours post administration of the FICB. Thus, in order to power the study to answer the objectives, a samples size was computed using the clinical trial formula (Hulley, Newman, Grady, Browner, & Cummings, 2007).

$$n = 2 \times \left(\frac{Z_{1-\beta} + Z_{1-\alpha/2}}{\nabla} \right)^2$$

The effect size ∇ is a ratio of differences in mean pain score between the intervention arm and the control arm to the pooled standard deviation of the two study arm and the corresponding quartiles and percentiles of the standard normal distribution.

The study was designed to be able to detect a 3-point pain score difference between the intervention arm and the control arm under various standard deviations. That is, the researcher assumed an effect size ranging from 0.3 to 3 points (Table 2).

Table 2: Sample size under 95% power, 5% type I error, and various effect size assumptions

Power	Type I Error	Difference	SD	Effect Size	Sample size per arm	Overall sample size	Correction for failure rate of 20%
80%	5%	3	1	3	2	4	6
			2	1.5	7	14	18
			3	1	16	32	40
			4	0.75	28	56	70
			5	0.6	44	88	110
			10	0.3	175	350	438

Based on the resources and the availability of the numbers within the study period, the sample size that was sufficient to answer the objective with 80% power and the minimum possible effect size of 0.75 while accounting for failure rate of 20% was 70. The effect size of 0.75 was chosen as minimum clinically meaningful differences in pain score between any two patients per unit standard deviation. This sample size was also adequate for 15^0 hip flexion, as studies done elsewhere showed that 21 patients were need to adequately show a 30% difference in pain score (Foss, Kristensen, Bundgaurd, Bak, & Herring, 2007).

3.6 Sampling

The sample technique for the study was simple randomized sampling. Computer generated random numbers from 1 to 70 were sealed in opaque envelopes. Every patient who consented to be include in the study, a sealed opaque enevelope was broken that the allocated them into the intervention arm or the control arm.

3.7 Data Analysis

Data were analyzed using the software for statistical version STAT 13 SE (College Station Texas 77845 USA).

Categorical variables: gender, diagnosis, ASA classification, anesthesia, surgical treatment and surgical approach were summarized as frequency tables and corresponding percentages.

Continuous variables: age, pain score with limb in anatomical position and pain score with limb at 15 degrees flexion leg were summarized as mean and the corresponding standard deviation, if the Gaussian assumptions were satisfied, or in median and inter quartile range- if the assumption was not met.Patients were analyzed based on the treatment they actually received and pain scores between the two were compared using a Z-test, if Gaussian assumption held for the score, or using two samples Wilcoxon rank sum test.

The effect were determined as the difference in the pain score with limb in anatomical position and pain score with the limb at 15^0 leg flexion between the two treatment groups.

The estimates were reported alongside the corresponding 95% confidence interval. Results were presented using tables and graphs.

3.8 Data and Safety Monitoring Board

The Data and Safety Monitoring Board (DSMB) was constituted. The committee constituted of chairman form the orthopedics department, three members a consultant, orthopedic surgeon, consultant anesthesiologist and a statistician.

3.9 Fascia Iliaca Compartment Block administration technique

In this study, the landmark/ "two pop" technique was used. This technique was simple, easy to learn, did not require much equipment and would be practical to implement at MTRH. After a verbal explanation and an informed written consent from the patient, the patient was requested to lie supine. The FICB was administered at the post-operative limb. An imaginary line was drawn from the anterior superior iliac spine to the pubic tubercle. The line was then divided into thirds. One centimeter distal to the point was the site of drug administration. The femoral artery was palpated to ensure that the vessels were medial to the point of entry. The area was then cleaned with a cholohexidine swab. A blunt beveled needle with 20cc and 10cc syringe was used to inject a weight adjusted dose of a local anesthesia. Once through the skin the needle was angled at 60 degrees directing the tip cranially. The needle was then advanced, keeping it in the sagittal plane to avoid injury to the vessels, until two distinct pops are felt. The first "pop" was for the fascia lata and the second "pop" for the fascia iliaca. The needle angle was then reduced to 30^0 and advanced another 1-2mm. Once in the fascia iliaca compartment, aspiration was done to ensure that one was not in a vessel. With negative aspiration, the local anesthesia was then injected and after each 5mls was administered, aspiration was repeated. This procedure was repeated until the entire drug was successfully administered. This ensured that at all times that the needle was not in a vessel.

PROCEDURE TAKEN BEFORE BLOCK ADMINISTRATION

1) The procedure was explained to the patient a day before surgery while in the ward and a full history of any adverse reaction to drugs was taken and noted in the patient's file.
2) An Informed and written consent was then gotten from the patient while in the ward.
3) While in the post-anesthesia care unit the procedure was explained to the patient once they were fully conscious.
4) Patients who received spinal anesthesia, sensation for the T12 and L1 dermatome was tested for to ensure spinal anesthesia had worn off.
5) All patients had an intravenous line access and intravenous fluids administered
6) Vital signs: blood pressure, heart rate, respiratory rate and temperature were recorded before drug administration.
7) Drug dosage were calculated by the researcher administering FICB with a theater nurse and this was counter checked by a clinician in theater.
8) The technique described above for FICB was followed.
9) Vital signs were recorded again 30 minutes after administration of the drug.
10) Procedure notes were documented in the patient's file.

Equipment used included;

- Chlorohexidine swab
- 18 gauge to 22 gauge needle
- 20cc and 10cc syringes
- Local anesthetic:0.5% bupivacaine 0.35ml/kg (bupivacaine drug batch number:D1067)
- Normal saline
- Sterile Gloves
- Metallic Object (The metallic handle of a patella hammer)

3.10 Training

The principle investigator underwent a 2 day training on FICB administration. . The training was carried out at Machakos County Hospital under the guidance and supervision of a consultant anesthesiologist. . The training was undertaken once the proposal was approval from the International Research Committee had been given.

All data collectors underwent a one day training to familiarize them with the data collection form at the commencement of the study.

3.11 Ethical Considerations

An Institution Review Research Committee approval was sought (Appendix 5).

Patients were informed on the research that was carried out and an informed consent (Appendix 1) of the benefits and risks of the study was signed upon patients consent to be included in the study.

The research was completely voluntary, and patients were not hindered from withdrawing from the study if they so wished.

Confidentiality was maintained at all times during study and the patients were allowed access to the results.

The study was funded by the Kenyan Government National Research Fund. However, the data collection, analysis and results of this study were not affected in any way.

3.12 Study Limitation

- **Responses bias**: Due to the single blinded nature of the study, patients in Group A were likely to report lower pain scores. This was mitigated by assessing pain using multiple techniques.

CHAPTER FOUR: RESULTS

4.1 Statistical Data Analysis

Age, pains scores with the limb in anatomical positions and pain scores with the limb at 15^0 flexion were summarized using median (IQR) and mean (SD) respectively. . Frequency table and corresponding percentages were used to summarize gender, diagnosis, ASA classification, anesthesia, surgical treatment and surgical approach.

The mean pain score between Group A and Group B were compared using independent student T-test. Cohen's D effect sizes were calculated for the mean differences at each time point. The trends in the pain score across time for the two groups were presented using line graphs. Data analysis was done using STATA version 13 SE (College Station Texas 77845 USA).

4.2 Results

4.2.1: Comparison of the Demographic and Clinical Characteristics between the Group A and Group B

Seventy patients were recruited; 35 in the Group A and 35 in Group B. The demographic and other enrollment characteristics were documented for both Groups. The results were compared as shown in Table 3.

Table 3: Comparison of the demographic and clinical characteristics between Group A and Group B

		Treatment Group		
Variable	**N**	**Group A (N=35)**	**Group B (N=35)**	**p-value**
Age (Years), Median (IQR)	70	67.0 (49.0, 75.0)	70.0 (60.0, 78.0)	0.559[w]
Range (Min. - Max.)		22.0 - 89.0	25.0 - 100.0	
Gender, n (%)				
Female		16 (45.7%)	15 (42.9%)	
Male	70	19 (54.3%)	20 (57.1%)	0.810[c]
Diagnosis, n (%)				
Intertrochanteric		14 (40.0%)	12 (34.3%)	
NOF	70	19 (54.3%)	21 (60.0%)	0.923[f]
Subtrochanteric		2 (5.7%)	2 (5.7%)	
ASA				
1		8 (22.9%)	11 (31.4%)	
2	70	22 (62.9%)	21 (60.0%)	0.603[f]
3		5 (14.3%)	3 (8.6%)	
Anesthesia				
General		16 (45.7%)	18 (51.4%)	
Spinal	70	19 (54.3%)	17 (48.6%)	0.632[c]
Surgical treatment				
Angle blade		5 (14.3%)	3 (8.6%)	
Bipolar		19 (54.3%)	21 (60.0%)	
DHS	70	3 (8.6%)	3 (8.6%)	0.969[f]
IM		1 (2.9%)	1 (2.9%)	
PFN		7 (20.0%)	7 (20.0%)	
Procedure				
Lateral		19 (54.2%)	15 (42.9%)	
Anterolateral	70	13 (37.1%)	13 (37.1%)	0.795[c]
Posterior		3 (8.6%)	7 (20.0%)	

[c] Pearsons' Chi-Square test, [f] Fisher's exact test, [w] Wilcoxon rank-sum test

The median age for the patients in Group A was 67.0 (IQR: 49.0, 75.0) while the median age for the patients in Group B was 70.0 (IQR: 60.0, 78.0). The two sample Wilcoxon rank sum test for the difference in the age distribution showed that the two groups were similar, p = 0.559. The proportion of the male patients in Group A was similar to that of Group B, 54.3% versus 57.1%, p = 0.810. There was no statistical

significance difference in the diagnosis and ASA classification between patients in Group A and Group B, p=0.923 and p=0.603, respectively. The proportion of the patients who had general anesthesia in Group A was similar to that of Group B, 45.7%% vs. 51.4%, p = 0.632.The distribution of the patients based on the surgical treatment and approach were similar between Group A and Group B, with p = 0.969 and p=0.795, respectively.

4.2.2 Postoperative Pain Intensity, Using the Numerical rating Scale, after hip surgery with limb in anatomical position

Table 4: Comparison of the pain scores between Group A and Group B with limb in anatomical position

		Treatment Group			
		Group A	**Group B**		
Variable	**N**	**(N=35)**	**(N=35)**	**p-value**	**Cohen's D Effect Size (95% CI)**
Time (Hours) post anesthesia		Mean (SD) Pain score			
2 hours	70	4.5 (1.9)	8.4 (0.8)	<0.0001	2.6 (1.9, 3.2)
4 hours	70	2.7 (2.1)	7.1 (1.1)	<0.0001	2.6 (1.9, 3.2)
6 hours	70	3.9 (1.5)	6.0 (1.6)	<0.0001	1.4 (0.8, 1.9)
8 hours	70	4.8 (0.9)	4.9 (1.3)	0.659	0.1 (-0.4, 0.6)

At two, four and six hours FICB administration the mean pain score for Group A was significantly lower than that of the Group B, 4.5 (SD: 1.9) versus 8.4 (0.8), p <0.0001; 2.7 (SD: 2.1) versus 7.1 (SD: 1.1), p <0.0001; and 3.9 (SD: 1.5) versus 6.0 (SD: 1.6), p <0.0001 respectively. There was no sufficient evidence from the data to demonstrate a difference in mean pain score between Group A and Group B at 8 hours FICB administration, 4.8 (SD: 0.9) vs. 4.9 (SD: 1.3), p = 0.659 (Table 4.2.2). The strength of the FICB declined across the time as demonstrated by the Cohen's D effect size.

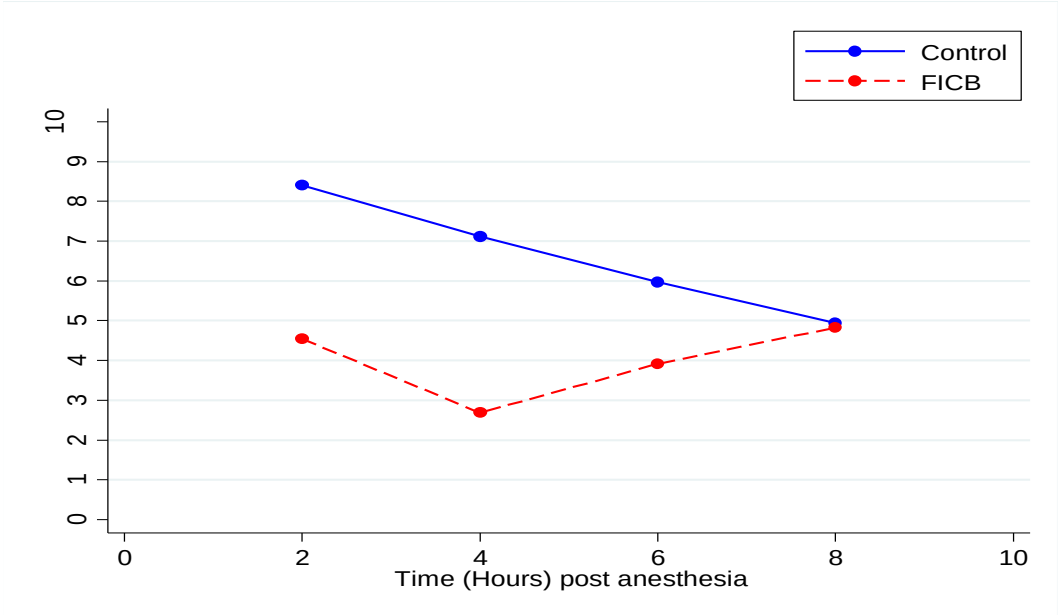


Figure 4: Mean pain score with limb in an anatomical position by the treatment groups across the time

The pain score for Group B declined steadily across all the time points. The mean pain score for Group A declined from 4.5 to 2.7 at 4 hours after FICB administration then increased to 3.9 and 4.8 at 6 and 8 hours after FICB administration. The mean pain score for the patients in Group A was lower than that of Group B at all the time points (Figure 4).

4.2.3 Pain Score, Using the Numerical Rating Scale, with limb in 15^0 flexion.

Table 5: Comparison of the pain scores between Group A and Group B with the limb at 15^0 Flexion.

		Treatment Group			
		Group A	Group B		
Variable	**N**	**(N=35)**	**(N=35)**	**p-value**	**Cohen's D Effect Size (95% CI)**
Time (Hours) post anesthesia		Mean (SD) Pain score			
2 hours	70	5.5 (1.5)	9.2 (0.6)	<0.0001	3.3 (2.6, 4.0)
4 hours	70	3.2 (2.9)	8.4 (1.0)	<0.0001	2.4 (1.8, 3.0)
6 hours	70	4.0 (2.0)	7.1 (1.2)	<0.0001	1.9 (1.4, 2.5)
8 hours	70	5.9 (0.9)	6.1 (1.1)	0.4599	0.2 (- 0.3, 1.0)

With the limb at 15^0 flexion, there was evidence that the degree of pain was substantially lower for Group A as compared to Group B at 2,4, and 6 hours.. At 2, 4 and 6 and hours after FICB administration the mean pain score for Group A was significantly lower than that of Group B. The pain scores at were 5.5 (SD: 1.5) versus 9.2 (0.6), p <0.0001; 3.2 (SD: 2.9) versus 8.4 (SD: 1.0) p <0.0001; 4.0 (SD: 2.0) versus 7.1 (SD: 1.2) p <0.000, respectively. There was no sufficient evidence from the data to demonstrate a difference in mean pain score between Group A and Group B at 8 hours after FICB administration, 5.9 (SD 0.9) versus 6.1 (SD 1.1), p=0.4599 (Table 4.2.3). The strength of the FICB declined across the time as demonstrated by the Cohen's D effect size.

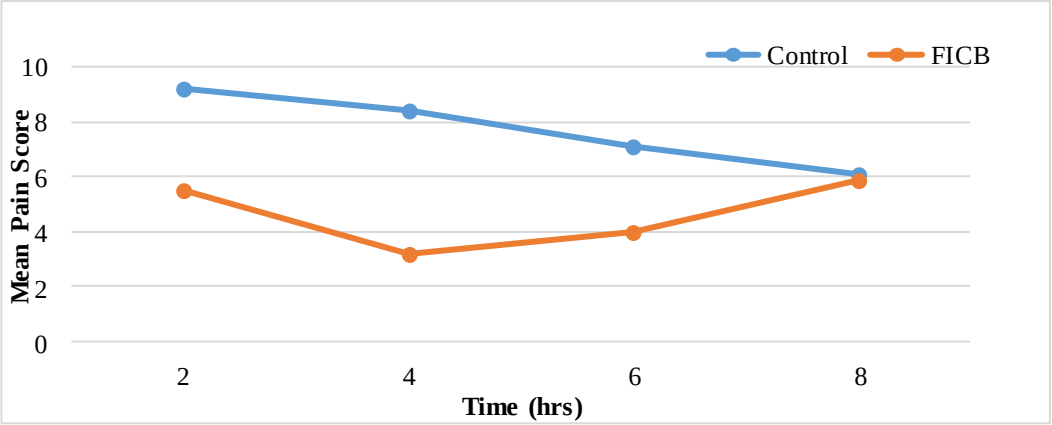


Figure 5: Mean pain score for leg in a lifted position by the treatment groups across the time

The pain score for Group B declined steadily across all the time points. The mean pain score for Group A declined from 5.5 to 3.2 at 4 hours post FICB administration then increased to 4.0 and 5.0 at six and eight hours post FICB administration. The mean pain score for the patients in Group A was lower than that of Group B at all the time points (Figure 5).

4.2.4 Failure Rate.

A failed FICB was defined a no reduction of 3 points on the NRS 15minutes after block administration and a normal sensation to a cold metallic object. A total of 6 FICB failed in the study. The failure rate was 17.1% (n=6).

CHAPTER FIVE: DISCUSSION

5.1 Postoperative Pain Intensity, using the Numerical rating Scale, after hip surgery when the limb is at anatomical position or flexed at 15 degrees.

Severe postoperative pain is often observed among orthopedic patients. This necessitates the use of effective analgesia to decrease morbidity, facilitate postoperative rehabilitation and reduce postoperative hospital discharge time. This study assessed the efficacy of FICB in post-operative pain management by comparing pain scores between those on FICB versus standard of care. Mean pain scores were compared when the limb was at an anatomical position and when flexed at fifteen degrees using numerical rating scale at 2, 4, 6 and 8 hours following surgery. The difference in mean scores between the intervention and control groups were found to be statistically significant ($p<0.001$). These findings build on those from a Spanish observational study conducted among 41 post hip-surgery patients (Arrola, Telletxea, Bourio, Maguregui, & Larracoechea, 2009). When pain was assessed within the first 24 hours using a visual analogue scale, its intensity was significantly lower ($p<0.001$) among those who had a two-pop technique used to administer a single shot of 0.45% ropivacaine FICB (blocking group) compared to the control group. Similar findings were also reported in Japan among 56 post-hip surgery patients (Fujihara *et al.*, 2013). In the Japanese study, mean pain scores were assessed using the Visual Analog Scale after 10 minutes, 6 hours and 10 hours of administration. The mean pain scores at 6 hours were lower in the FICB compared to the control group just like in the current study. In a Chinese study assessing the efficacy of continuous postoperative analgesia after hip fracture surgery (Nie *et al.*, 2015), mean postoperative pain scores assessed using the numerical rating scale at 2, 4, 6, 8 and 12 hours after analgesia administration were significantly lower ($p=0.039$) among FIBC group compared to

systemic analgesia (paracetamol, diclofenac and PCIA morphine) alone. A meta-analysis evaluating the efficacy and safety of FICB in alleviating pain after lower limb surgery was conducted on the findings from seven clinical trials (Yang *et al.*, 2017). The results revealed that patients receiving FICB had a statistically significant lower mean pain score at 4, 12 and 24 hours compared to those who did not. This finding matches that of the current study where the least pain score was demonstrated after four hours of FICB administration. The block is therefore an effective and safe method for alleviate acute pain following lower limb surgery.

Despite the similarities of the current study to previously reported ones, this study mean pain score reduction finding contrasts that reported from the New York's Roosevelt Hospital Center that did not demonstrate a reduction in pain intensity after hip surgery following ultrasound guided FICB of 0.5% ropivacaine (Shariat *et al.*, 2013). This discordance could be attributed to the possibility of interuser variability during ultrasound guided FICB administration and low dose ropivacaine that is inadequate for analgesia. Longer duration of analgesia has also been demonstrated among patients on FICB that lasts eight to ten hours following a single shot block combined with epinephrine (Lopez *et al.*, 2003). As opposed to the Lopez et al study, the mean pain scores among those in the intervention arm was optimum in the first fours but began declining to the eighth hour. This could be attributed the fact that co-administration of epinephrine increases FICB's half-life and prolongs the duration of efficacy as was demonstrated in the Roosevelt Hospital's study findings.

Because anesthesia of the hip joint could be affected by the fascia iliaca compartment block anatomy, negative analgesic findings could be due to the influence of innervation from the sacral plexus and the limitations of the more distal approaches when the landmark block administration technique are considered (Monzon, Iserson

and Vazquez, 2007). Furthermore, at times the part of the surgical incision may extend outside the dermatome of the lateral Cutaneous Nerve of the thigh's nerve root (Jones *et al.*, 2019). Irrespective of the administration approach adopted, the obturator nerve is most frequently missed in two thirds of the cases leaving the Femoral Nerve the most reliably blocked (Jakobsson *et al.*, 2015).

5.2 Fascia iliaca compartment block failure Rate

Previous studies have also reported FICB failure rate as low as 3% (Leeper *et al.*, 2012) to as high as 35% (Hanna, Gulati and Graham, 2014). In this study, 17.1% (n=6) of the study participants in the intervention arm were deemed to have failed. The low failure rate reported in this study when compared to a British study (Hanna, Gulati and Graham, 2014) could be attributed to the limited inter-user variability in the block administration, as only a single resident was involved in the administration process. Lower failure rates of 10% were associated with limited inter-user variability in France (Dalens, Vanneuville and Tanguy, 1989), where a femoral three in one block was administered by a single anesthetist to limit the likelihood of inter-user variability. The lowest failure rate (3%) was documented in a British study attributed it to the fact that the block was performed by single trained personnel further reducing inter-person variability in the block's administration (Leeper *et al.*, 2012).

Even though most of the previously reviewed studies attribute failure to inter-user variability and challenges in the learning curve, this study demonstrates that a posterior surgical approach is significantly associated with FICB failure.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Pain relief was superior for the first 6 hours after surgery in patients who received a Fascia iliaca compartment block as an analgesic with the limb in anatomical position and at 15^0 flexion. There was no statistical significant difference in pain score at 8 hours between the two groups. The failure rate was low at 17.1%.

6.2 Recommendations

1. Training on FICB be introduce at MTRH for orthopedic residents in a bid to improve postoperative pain management.
2. Fascia Iliaca Compartment Block be adopted into our postoperative analgesia regiment
3. Further studies looking into longer acting analgesic options be conducted.

REFERENCES

Ballantyre, J. C. (2011). Managing Acute Pain in the Developing World. *International Association of the Study of Pain*, 1-6.

Bang, S., Chung, J., Jaejung, J., Bak, H., & Kim, D. (2016). Efficacy of Ultrasound-guided fascia iliaca compartment block after hip hemiarthroplasty. *Medicine*, 95,39(e5018).

Becker, D. E., & Reed, K. L. (2012). Local anesthetics: review of pharmacological considerations. *Anesthesia progress*, *59*(2), 90-102.

Breivik, H. (1998). Postoperative pain management: why is it difficult to show that it improves outcome?. *European Journal of Anaesthesiology (EJA)*, *15*(6), 748-751.

Brennan, F., Carr, D. B., & Cousins, M. (2007). Pain Management: A Fundamental Human Right. *International Anesthesia Research Society*, 105:206-21.

Chesters, A., & Atkinson, P. (2014). Fascia iliaca block for pain relief from proximal femoral fracture in the emergency department: a review of the literature. *Emergency medicine journal*, *31*(e1), e84-e87.

Dalens, B., Vanneuville, G., & Tanguy, A. (1989). Comparison of the fascia iliaca compartment block with the 3-in-1 block in children. *Anesthesia & Analgesia*, *69*(6), 705-713.

Deniz, S., Atım, A., Kürklü, M., Çaycı, T. and Kurt, E., 2014. Comparison of the postoperative analgesic efficacy of an ultrasound-guided fascia iliaca compartment block versus 3 in 1 block in hip prosthesis surgery. *Ağrı - The Journal of The Turkish Society of Algology*, 26(4), pp.151-157.

Desmet, M., Vermeylen, K., Van Herreweghe, I., Carlier, L., Soetens, F., Lambrecht, S., ... & Van de Velde, M. (2017). A longitudinal supra-inguinal fascia iliaca compartment block reduces morphine consumption after total hip arthroplasty. *Regional Anesthesia & Pain Medicine*, *42*(3), 327-333.

Dhanwal, D. K., Dennison, E. M., Harvey, N. C., & Cooper, C. (2011). Epidemiology of hip fracture: worldwide geographic variation. *Indian journal of orthopaedics*, *45*, 15-22.

Dochez, E., van Geffen, G. J., Bruhn, J., Hoogerwerf, N., van de Pas, H., & Scheffer, G. (2014). Prehospital administered fascia iliaca compartment block by emergency medical service nurses, a feasibility study. *Scandinavian journal of trauma, resuscitation and emergency medicine*, *22*(1), 1-7.

Ekstein, M. P., & Weinbroum, A. A. (2011). Immediate postoperative pain in orthopedic patients is more intense and requires more analgesia than in post-laparotomy patients. *Pain Medicine*, *12*(2), 308-313.

Elkhodair, S., Mortazavi, J., Chester, A., & Pereira, M. (2011). Single fascia iliaca compartment block for pain relief in patients with fractured neck of femur in the emergency department: a pilot study. *European journal of emergency medicine*, *18*(6), 340-343.

Fishman, S. M. (2007). Recognizing pain management as a human right: a first step.

Fong, A., & Schug, S. A. (2014). Pathophysiology of pain: a practical primer. *Plastic and reconstructive surgery*, *134*(4S-2), 8S-14S.

Foss, N. B., Kristensen, B. B., Bundgaard, M., Bak, M., Heiring, C., Virkelyst, C., ... & Kehlet, H. (2007). Fascia iliaca compartment blockade for acute pain control in hip fracture patientsa randomized, placebo-controlled trial. *Anesthesiology: The Journal of the American Society of Anesthesiologists*, *106*(4), 773-778.

Fujihara, Y., Fukunishi, S., Nishio, S., Miura, J., Koyanagi, S., & Yoshiya, S. (2013). Fascia iliaca compartment block: its efficacy in pain control for patients with proximal femoral fracture. *Journal of Orthopaedic Science*, *18*(5), 793-797.

Goitia, A. L., Telletxea, S., Martínez, B. R., Arízaga, M. A., & Aguirre, L. U. (2009). Fascia iliaca compartment block for analgesia following total hip replacement surgery. *Revista espanola de anestesiologia y reanimacion*, *56*(6), 343.

Goitia, A. L., Telletxea, S., Martínez, B. R., Arízaga, M. A., & Aguirre, L. U. (2009). Fascia iliaca compartment block for analgesia following total hip replacement surgery. *Revista espanola de anestesiologia y reanimacion*, *56*(6), 343.

Hanna, L., Gulati, A., & Graham, A. (2014). The role of fascia iliaca blocks in hip fractures: a prospective case-control study and feasibility assessment of a junior-doctor-delivered service. *International Scholarly Research Notices*, *2014*.

Høgh, A., Dremstrup, L., Jensen, S. S., & Lindholt, J. (2008). Fascia iliaca compartment block performed by junior registrars as a supplement to pre-operative analgesia for patients with hip fracture. *Strategies in trauma and limb reconstruction*, *3*(2), 65-70.

Huang, K. T., Owino, C., Gramelspacher, G. P., Monahan, P. O., Tabbey, R., Hagembe, M., ... & Vreeman, R. C. (2013). Prevalence and correlates of pain and pain treatment in a western Kenya referral hospital. *Journal of palliative medicine*, *16*(10), 1260-1267.

Hulley, S. B., Newman, T. B., Grady, D. G., Browner, W. S., & Cummings, S. R. (2007). *Designing a clinical trial research.* Philadelphia: Lippincott Williams & Wilkins.

Kent, M. L., Tighe, P. J., Belfer, I., Brennan, T. J., Bruehl, S., Brummett, C. M., ... & Edwards, D. (2017). The ACTTION–APS–AAPM Pain Taxonomy (AAAPT) multidimensional approach to classifying acute pain conditions. *Pain Medicine*, *18*(5), 947-958.

Kinyungu, E. N. (2010). Analgesia and Anesthesia in Pre-Colonial Africa. *Bulletin of anesthesia history*, *28*(2), 26-30.

Kumar, K., Pandey, R. K., Bhalla, A. P., Kashyap, L., Garg, R., Darlong, V., ... & Yadav, C. S. (2015). Comparison of conventional infrainguinal versus modified proximal suprainguinal approach of Fascia Iliaca Compartment Block for postoperative analgesia in Total Hip Arthroplasty. A prospective randomized study. *Acta Anaesthesiol Belg*, *66*(3), 95-100.

Kumie, F. T., Gebremedhn, E. G., & Tawuye, H. Y. (2015). Efficacy of fascia iliaca compartment nerve block as part of multimodal analgesia after surgery for femoral bone fracture. *World journal of emergency medicine*, *6*(2), 142.

Leeper, A. D., Brandon, P. T., Morgan, A. V. M., Cutts, S., & Cohen, A. M. M. (2012). Fascia iliaca compartment block reduces morphine requirement pre-operatively for patients with fractured neck of femur. *European Journal of Trauma and Emergency Surgery*, *38*(6), 673-677.

Leeper, A. D., Brandon, P. T., Morgan, A. V. M., Cutts, S., & Cohen, A. M. M. (2012). Fascia iliaca compartment block reduces morphine requirement pre-operatively for patients with fractured neck of femur. *European Journal of Trauma and Emergency Surgery*, *38*(6), 673-677.

Lopez, S., Gros, T., Bernard, N., Plasse, C., & Capdevila, X. (2003). Fascia iliaca compartment block for femoral bone fractures in prehospital care. *Regional Anesthesia & Pain Medicine*, *28*(3), 203-207.

Lopez, S., Gros, T., Bernard, N., Plasse, C., & Capdevila, X. (2003). Fascia iliaca compartment block for femoral bone fractures in prehospital care. *Regional Anesthesia & Pain Medicine*, *28*(3), 203-207.

Manjiani, D., Paul, D. B., Kunnumpurath, S., Kaye, A. D., & Vadivelu, N. (2014). Availability and utilization of opioids for pain management: global issues. *Ochsner Journal*, *14*(2), 208-215.

Masigati, H. G., & Chilonga, K. S. (2014). Postoperative pain management outcomes among adults treated at a tertiary hospital in Moshi, Tanzania. *Tanzania journal of health research*, *16*(1).

Monzon, D. G., Iserson, K. V., & Vazquez, J. A. (2007). Single fascia iliaca compartment block for post-hip fracture pain relief. *The Journal of emergency medicine*, *32*(3), 257-262.

Morrison, R. S., Magaziner, J., Gilbert, M., Koval, K. J., McLaughlin, M. A., Orosz, G., ... & Siu, A. L. (2003). Relationship between pain and opioid analgesics on the development of delirium following hip fracture. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *58*(1), M76-M81.

Mulroy, M. (2014). A history of regional anesthesia. In *The wondrous story of anesthesia* (pp. 859-870). Springer, New York, NY.

Mwaka, G., Thikra, S., & Mung'ayi, V. (2013). The prevalence of postoperative pain in the first 48 hours following day surgery at a tertiary hospital in Nairobi. *African health sciences*, *13*(3), 768-776.

Mysliwy, P., & Hladki, W. (2010). Fascia Iliaca Compartment Block. *OSTRY DYZUR, 3* (1), 5-6.

Newman, B., McCarthy, L., Thomas, P. W., May, P., Layzell, M., & Horn, K. (2013). A comparison of pre-operative nerve stimulator-guided femoral nerve block and fascia iliaca compartment block in patients with a femoral neck fracture. *Anaesthesia*, *68*(9), 899-903.

Nie, H., Yang, Y. X., Wang, Y., Liu, Y., Zhao, B., & Luan, B. (2015). Effects of continuous fascia iliaca compartment blocks for postoperative analgesia in patients with hip fracture. *Pain Research and Management*, *20*.

Philip, W., Kuo, P. C., & Schroeder, R. A. (2007). The postoperative care of the surgical patient. DO David : First Exposure to General Surgery *Surgery (Oxford)*, 22(6), pp.141-144.

Pinson, S. (2015). Fascia Iliaca (FICB) block in the emergency department for adults with neck of femur fractures: A review of the literature. *International emergency nursing*, *23*(4), 323-328.

Powell, R. A., Kaye, R. M., Ddungu, H., & Mwangi-Powell, F. (2010). Advancing drug availability—experiences from Africa. *Journal of pain and symptom management*, *40*(1), 9-12.

Range, C., & Egeler, C. (2010). *Fascia Iliaca Compartment Block: Landmark and Ultrasound Approach.* Swansea: Christine Ranger.

Ritcey, B., Pageau, P., Woo, M. Y., & Perry, J. J. (2016). Regional nerve blocks for hip and femoral neck fractures in the emergency department: a systematic review. *Canadian Journal of Emergency Medicine*, *18*(1), 37-47.

Shariat, A. N., Hadzic, A., Xu, D., Shastri, U., Kwofie, K., Gandhi, K., ... & Unis, D. (2013). Fascia lliaca block for analgesia after hip arthroplasty: a randomized double-blind, placebo-controlled trial. *Regional Anesthesia & Pain Medicine*, *38*(3), 201-205.

Silk, Z., Allen, W. L., Waters, T. S., & Koomson, A. (2012). Fascia iliaca compartment block should be taught to more surgeons in training to improve pain control for patients with femoral fractures. *International Journal of Surgery*, *8*(10), S62.

Sinatra, R. (2010). Causes and consequences of inadequate management of acute pain. *Pain medicine*, *11*(12), 1859-1871.

Stevens, M., Harrison, G., & McGrail, M. (Dec 2007). Fascia Iliaca Compartment Block for Femoral Bone Fractures in Prehospital Care. *Aanesth Intensive Care*, 35 (6),949-52.

Waldam, C. (2017). The Role of Fascia Iliaca Compartment in Total Hip Arthroplasty. *SM Journal of Anesthesia*, Vol 3, Issue 1, Page 10-14.

Yang, L., Li, M., Chen, C., Shen, J., & Bu, X. (2017). Fascia iliaca compartment block versus no block for pain control after lower limb surgery: a meta-analysis. *Journal of Pain Research*, *10*, 2833.

Yang, L., Li, M., Chen, C., Shen, J., & Bu, X. (2017). Fascia iliaca compartment block versus no block for pain control after lower limb surgery: a meta-analysis. *Journal of Pain Research,* 10,2833-2841.

APPENDICES

Appendix 1- Consent Form

FASCIA ILIACA COMPARTMENT BLOCK FOR ANALGESIA FOLLOWING HIP SURGERY AT MTRH

INVESTIGATOR- NELLY MAOGA OF P.0.BOX 176-80100 MOMBASA, KENYA

I……..of P.O. Box…….Tel……...

Hereby consent to participate in this study at MTRH. The study has been hereby explained to me by Nelly Moaga/ appointed assistant.

I am volunteering to participate in this study and all benefits and risks have been explained to me. I'm informed that I have the right to withdraw from the study at any point. If I wish to withdraw, I'm still entitled to treatment at MTRH. I'm assured that the information will be confidential and I'm entitled to access of the results.

Name of participant……

Signature……

Date……

Name of witness…….

Signature……

Date…….

Mimi_____

S.L.P_____, Nambari ya Simu_____

Najitolea kwa hiari yangu mwenyewe kutoa kibali cha kujihusisha katika utafiti uliotajwa hapo juu unoaendelezwa katika MTRH. Nimepokea maelezo ya tafsili kuhusu utafiti huu kutoka kwa Dr. Nelly Maoga katika lugha, kanuni na masharti ninayoelewa vyema. Nimehakikishiwa kuwa, sitadhurika kamwe kutokana na kujihusisha kwangu katika utafiti huu.Ilibainishwa kuwa kujihusisha katika utafiti huu ni kwa hiari na nina uhuru wa kujiondoa wakati wowote ule bila ya kuhujumiwa hasa kuhusu haki yangu ya kupokea matibabu katika MTRH. Zaidi ya hayo, nilihakikishiwa kuwa, kanununi zote za maadili ya utabibu,uhuru, haki, na manufaa zitazingatiwa katika utafiti huu.

Jina la Mhojiwa_____

Sahihi _____

Tarehe _____

Jina la shahidi _____

Sahihi _____

Tarehe _____

Appendix 2: Questionnaire

I) Demographic data

Case identity……

Gender…….

Age……...

II) Diagnosis……

ASA……

Anesthesia……

Surgical treatment……

Surgical Approach……...

Time analgesia was administered……

III) Pain score: on a scale of 0 to 10 what is the level of pain are you feeling? (0 being no pain and 10 being most pain)

(i) 30 minutes……..

Pain scores after surgery

(ii) 2 hours……

(iii)4 hours……

(iv)6 hours……

(v) 8 hours……

(IV) Pain score on 15^0 leg lift (measured using a goniometer).

(i) 30 minutes……

Pain score after leg lift after surgery

(ii) 2 hours…….

(iii)4 hours…….

(iv)6 hours…….

(v) 8 hours…….

Appendix 3: Work plan

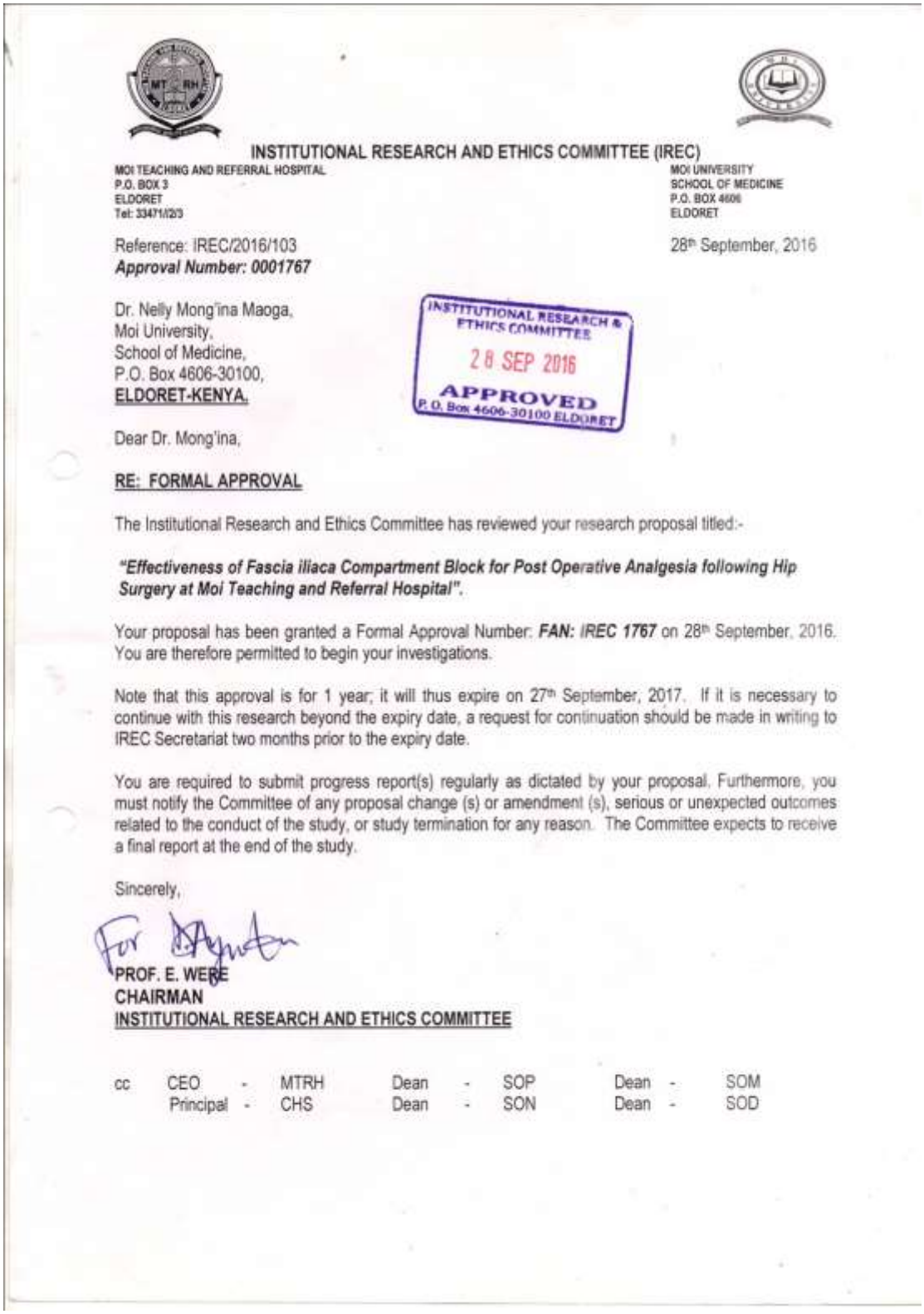
YEAR	**2015**		**2016**	**2017**	**2018**		
ACTIVITY	**Nov**	**Dec**	**Jan-June 2017**	**July- Dec**	**Jan-March**	**April**	**May-Dec**
Proposal Writing							
Proposal Presentation and submission							
Data Collection							
Data Analysis							
Thesis Writing							
Draft Presentation							
Thesis Submission							

Appendix 4: Budget

Item		Unity cost (Ksh)	Quantity	Total amount(Ksh)
Data Collector	2			105,00
Drugs	Bupivacaine	287	35	10,045
	Normal Saline	70	70	4,900
	Morphine	157	70	10,990
	Diclofenac	68	70	4,760
	Paracetamol	660	70	46,200
Resuscitation drug	Propofol	313	3	939
	Thiopental	219	3	657
	Succinlycholine	53	3	159
	Epinephrine	2793	3	8,379
	Amidorano	233	3	399
	Lipid emulsion 20% at 500mls	6000	2	12,000
	Dipghenyllaramine Intravenous 25-30mg	230	3	960
	Methylprednisolone 125mg	560	1	560
	Naloxone	665	1	665

Equipment	Chlohexidine swabs	15	70	1000
	18-22 gauge needles	87	70	910
	20 cc syringe	30	35	1050
	10 cc syringe	10	70	700
	Gloves	3300	2 box sterile gloves	6600
Stationary				10,000
Training				50,000
Publication Cost				20,000
Travel Eldoret to Machakos				5,000
Accommodation				15000
			total	421,873

Appendix 5: IREC Approvals



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/103
Approval Number: 0001767

28th September, 2016

Dr. Nelly Mong'ina Maoga,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
28 SEP 2016
APPROVED
P.O. Box 4606-30100 ELDORET

Dear Dr. Mong'ina,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Effectiveness of Fascia iliaca Compartment Block for Post Operative Analgesia following Hip Surgery at Moi Teaching and Referral Hospital".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1767*** on 28th September, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 27th September, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

For

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/103

29th July, 2016

Dr. Nelly Mong'ina Maoga,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
29 JUL 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Mong'ina,

RE: PROVISIONAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Effectiveness of Fascia iliaca Compartment Block for Post Operative Analgesia following Hip Surgery at Moi Teaching and Referral Hospital."

Your proposal has been granted ***one month provisional approval*** from 29th July, 2016 subject to ratification by IREC Full Board. Note that this is a preliminary approval and you are only allowed to set-up in readiness for the study but no recruitment should take place within this period until formal approval is granted.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2016/103
Approval Number: 0001767

28th September, 2018

Dr. Nelly Mong'ina Maoga,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
28 SEP 2018
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dear Dr. Mong'ina,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Effectiveness of Fascia Iliaca Compartment Block for Post Operative Analgesia following Hip Surgery at Moi Teaching and Referral Hospital".

Your proposal has been granted a Continuing Approval with effect from 28th September, 2018. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 27th September, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2016/103

28th September, 2017

Approval Number: 0001767

Dr. Nelly Mong'ina Maoga,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
28 SEP 2017
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Mong'ina,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Effectiveness of Fascia Iliaca Compartment Block for Post Operative Analgesia following Hip Surgery at Moi Teaching and Referral Hospital".

Your proposal has been granted a Continuing Approval with effect from 28th September, 2017. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 27th September, 2018. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference IREC/2016/103
Approval Number: 0001767

20th September, 2017

Dr. Nelly Mong'ina,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
20 SEP 2017
APPROVED
P.O. Box 4606 30100 ELDORET

Dear Dr. Mong'ina,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"Effectiveness of Fascia iliaca Compartment Block for Post Operative Analgesia following hip Surgery at Moi Teaching and Referral Hospital".

We note that you are seeking to make amendments as follows:-

1. To include all patients undergoing hip surgery regardless of whether they receive spinal or general anesthesia.
2. To administer fascia iliaca compartment block after hip surgery in the post anaesthetic care unit in theater.

The amendments have been approved on 20th September, 2017 according to SOP's of IREC. You are therefore permitted to continue with your research.

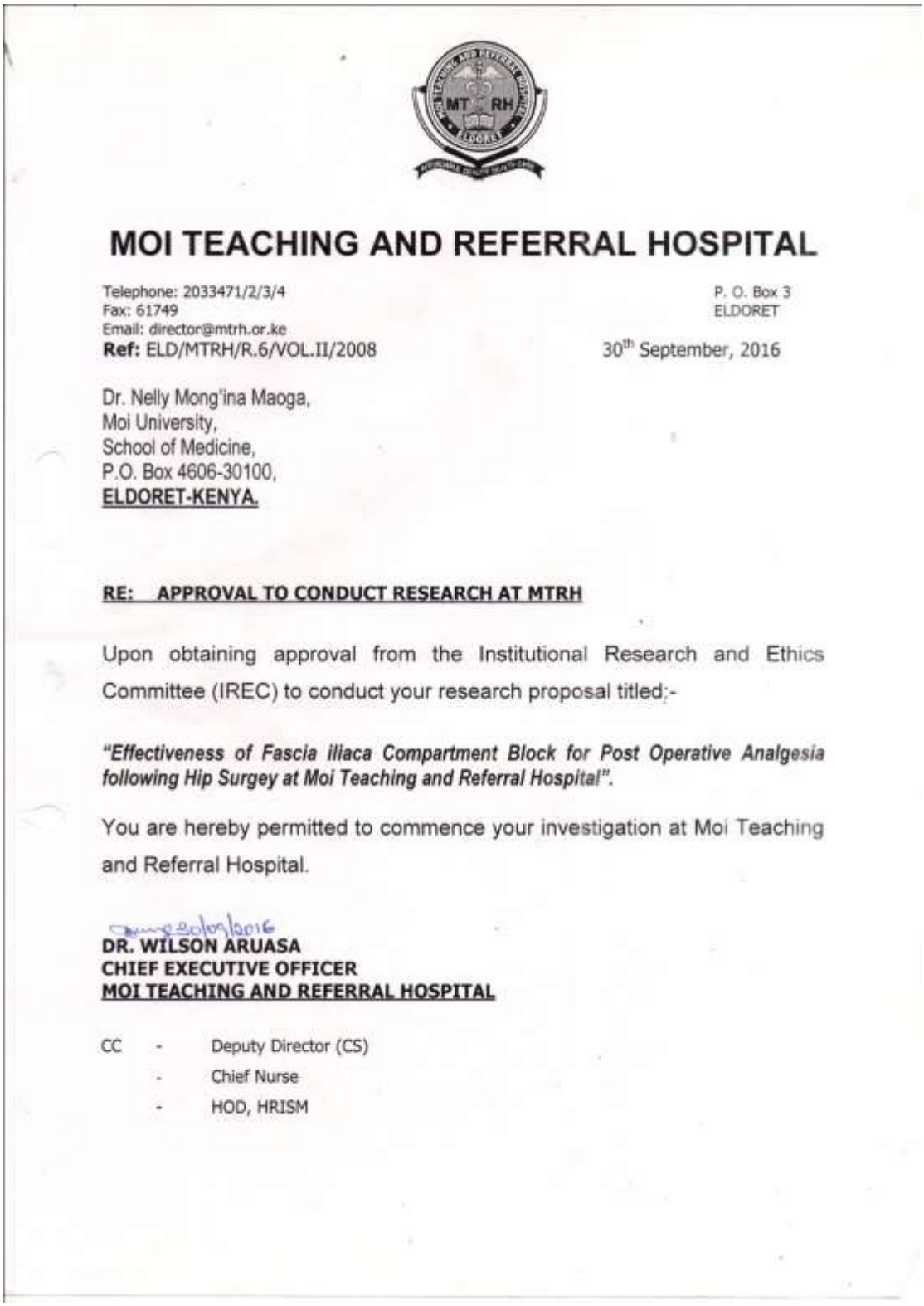
You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

for **PROF. E. WERE**
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH Dean - SPH Dean - SOM
Principal - CHS Dean - SOD Dean - SON

Appendix 6:MTRH Approval



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
Ref: ELD/MTRH/R.6/VOL.II/2008

P. O. Box 3
ELDORET

30th September, 2016

Dr. Nelly Mong'ina Maoga,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Effectiveness of Fascia iliaca Compartment Block for Post Operative Analgesia following Hip Surgey at Moi Teaching and Referral Hospital".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

30/09/2016
DR. WILSON ARUASA
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

National Research Fund

MOI UNIVERSITY

POSTGRADUATES PROGRAMME

FUNDS DISBURSED

THROUGH: -

STATE DEPATMENT OF UNIVERSITY EDUCATION,

MINISTRY OF EDUCATION

7	Nelly M. Maoga	Effectiveness of Fascia Compartment Block for Post-Operative Analelgesia following HIP Surgery at Moi Teaching and Referal Hospital	421,873