Open anterior mesh repair versus modified open anterior mesh repair for groin hernia in women. A double blinded randomized controlled trial.

December 2018

Title page

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The work will be conducted as collaboration between Makerere University, Uganda and Umeå University, Linköping University and Karolinska Institute, Sweden.

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Acronyms and Abbreviations

I/M HDSS Site	Iganga / Mayuge Districts Health and Demographic Surveillance
RRH	Regional Referral Hospital
GH	General Hospital
USD	United States Dollar
SSA	Sub-Saharan Africa
ASA	American Society of Anaesthesiologists

Operational definitions

Groin hernia	Inguinal and/or femoral hernia

Abstract

Background

Surgery has been considered too costly and with little impact on the burden of disease in resource limited settings. Research is refuting this belief and it has been found that surgical services are highly cost-effective and compare favourably with other prioritized areas in health care in such settings. Globally, 220 million people live with groin hernia. Around 20 million of these are women. Methods used for groin hernia repair in men, like the modified Bassini, the Lichtenstein and the Lockwood methods are not optimal in women who face elevated risks of recurrence following surgery compared to men.

Methods

In this double blinded randomised controlled trial, 440 women will be randomised into the control group (n=220) for the open anterior mesh repair or to the intervention group (n=220) for the modified open anterior mesh repair. The trial will be carried out in different hospitals in the country. Randomisation and allocation to the trial group will be carried out using a central computerised program. Primary endpoints are chronic pain and hernia recurrence. Secondary endpoints are patient satisfaction, costs and cost-effectiveness. A blinded observer will follow up the participants after two weeks, one year, and three years' post operatively.

Objective of the study

This study is undertaken to develop an improved method for and open groin hernia repair in women in Uganda and other resource constrained countries by comparing the open anterior mesh repair against the modified anterior mesh repair for groin hernias in Women. Very little evidence on hernia repair in women exists despite that this is a large patient group. The findings will be used to guide the writing of clinical guidelines as well as training of surgical providers, primarily in sub-Saharan Africa.

Introduction

1. Background to the study

Global surgery is a field of research, advocacy and policy making (Bickler and Spiegel, 2008). Five billion people lack access to safe surgery at an affordable cost when needed yet surgery contributes to one third of the global burden of disease (Meara *et al.*, 2015). Surgery has been believed to be too costly for low income settings but this is a misunderstanding as surgery is as cost-effective as other prioritised health care interventions (Bae, Groen and Kushner, 2011)(Debas *et al.*, 2006).

Only a fraction of the world's surgeries occur in low-income settings (Weiser *et al.*, 2008). This results in an accumulation of disease that could have been amenable by surgery. Many deaths could also be averted by surgery (Groen *et al.*, 2012). The associated loss in productivity will amount to over 20 trillion USD between 2015 and 2030. Expressed in proportion of GDP Low- and Middle Income Countries (LMICs) are most affected (Alkire *et al.*, 2015).

In this context, conditions that are common and that can be treated at low cost, with high cost-effectiveness even in smaller health facilities should be prioritised. Groin hernia is such a condition.

Over 200 million people live with a groin hernia worldwide and if left untreated, this condition causes considerable pain and also leads to 40,000 deaths per year (Beard *et al.*, 2015). Epidemiological studies among women have not been performed to determine the real burden of disease but a previous study in Eastern Uganda indicated groin hernias in women contributing 24% of groin hernia surgery volume (Löfgren *et al.*, 2014). A facility based study carried out in 29 hospitals in Uganda found that 16% of the groin hernia repairs were performed in women, mainly using tension techniques (manuscript). Tension groin hernia repairs have high rates of recurrence compared to mesh repair (M P Simons *et al.*, 2009).

Even for mesh hernia repair, the recurrence rate is higher in women than in men (Nilsson, Holmberg and Nordin, 2017). A possible explanation is that it is a result of femoral hernias being relatively more common in women than in men, and that these

may be overlooked during hernia repair. In high resource settings, laparoscopic repair with mesh implantation has been found to carry the lowest rates of recurrence in women and is therefore the recommended approach in women (Nilsson, Holmberg and Nordin, 2017)(The HerniaSurge Group, 2018). Through this method, both the inguinal and femoral regions can be inspected and hernias repaired. However, due to high costs of equipment and maintenance as well as long learning curves compared to open techniques, laparoscopic hernia repair will not be available to the majority of the patients in Sub-Saharan Africa and Uganda for a long time to come. Developing and evaluating an open method, designed for women and can be utilized in Uganda and other Sub Saharan countries is therefore an urgent priority.

2. Statement of the problem

Groin hernia repair is the commonest general surgical procedure performed globally (Beard *et al.*, 2015). It affects children, women and men but most research has been carried out in men. The risk of recurrence is higher in women than in men when the same methods are used (Nilsson, Holmberg and Nordin, 2017). In the emergency setting, mortality is higher for women than for men undergoing hernia repair (Nilsson, Stylianidis, Haapam??ki, *et al.*, 2007). This inequity warrants further investigation and correction.

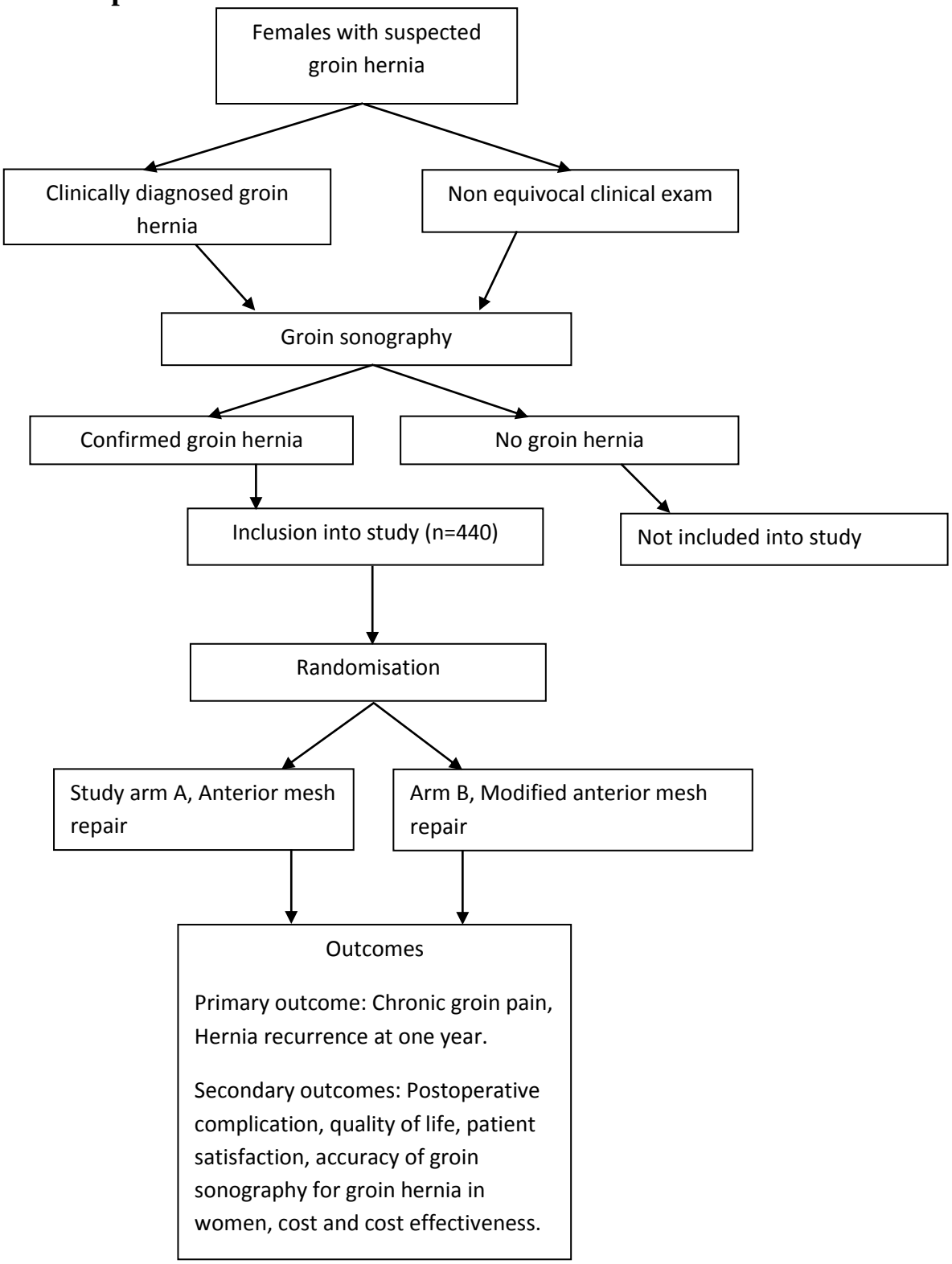
Laparoscopic approach is considered golden standard in mesh hernia repair in women (M. P. Simons *et al.*, 2009). This method is not available to the majority of the patients in sub-Saharan Africa or Uganda. An open method for repair of groin hernia in women, which is easy to learn, safe to use and with high cost-effectiveness is therefore called for.

The proposed study will investigate the use of a modified anterior mesh technique that will cater for both inguinal and femoral hernias, hoping that we can reduce recurrence and chronic groin pain after groin hernia repair in women.

3. Justification of the study

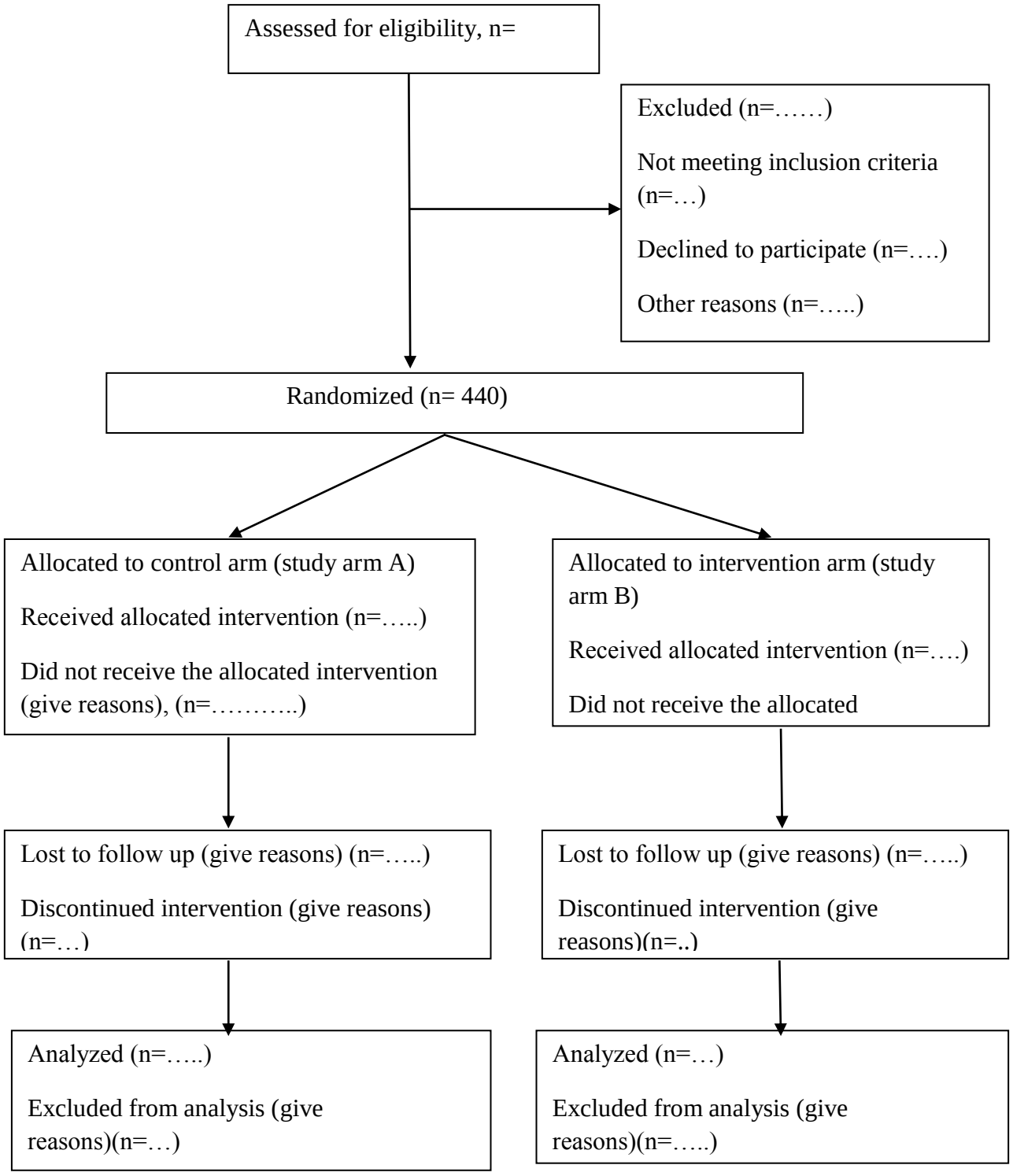
This study aims to improve outcomes after groin hernia repair in women. The findings will be used to promote a new method for groin hernia repair in women in Low Income Settings. Promotion of the method will also promote groin hernia surgery in women subsequently reducing morbidity and mortality associated with groin hernias.

4. Fig 1. Conceptual framework



4.1. Consort Flow Chart.

Fig. 2. Flow diagram of the progress through the phases of the study.



5. Research questions

i. What is the difference in safety and effectiveness of the open anterior mesh repair compared to the modified open anterior mesh repair for groin hernias in women?

ii. What is the difference in cost and cost effectiveness of the open anterior mesh repair compared to the modified open anterior mesh repair for groin hernias in women?

6. Objectives of the study

6.1. General objective of the study

The general objective of this study is to contribute with scientific evidence best practices in groin hernia repair in women.

6.2. The specific objectives are to

a) Evaluate and compare the outcomes after groin hernia repair using the open anterior mesh technique and the modified anterior mesh technique for groin hernia repair in women.

b) Calculate and compare costs and cost-effectiveness of this procedure (of the open anterior mesh technique with the modified anterior mesh technique for groin hernia repairs in women.

6.3. Hypothesis

There is no difference between the open anterior mesh repair and the modified open anterior mesh repair for groin hernias in women.

7. Literature review

Groin hernias in women can present as inguinal, femoral or inguinal femoral. Some of the factors associated with inguinal hernias in women in the United States of America are older age, rural residence, greater height, chronic cough and presence of an umbilical hernia(Ruhl and Everhart, 2007). These factors have not been studied in Uganda but groin hernias commonly present as groin swellings and they are also responsible for some pelvic pain in women(Perry and Echeverri, 2006). Persistent groin pain in women without a palpable lump should arouse suspicion of an occult hernia(Kark and Kurzer, 2008). Women have a high morbidity and mortality following groin hernias(Nilsson, Stylianidis, Haapam??ki, *et al.*, 2007) but also women have a higher risk of recurrence (inguinal or femoral than men) following an inguinal hernia operation due to a higher occurrence of femoral hernias(Nilsson, Holmberg and Nordin, 2017). It is therefore recommended that in female patients, the existence of a femoral hernia should be excluded in all cases of a hernia in the groin(M. P. Simons *et al.*, 2009).

Each year, over 20 million hernia repairs are undertaken worldwide and it is the world's most commonly performed general surgical procedure(The HerniaSurge Group, 2018). In high income settings, the lifetime risk of needing a groin hernia repair is 27% in men and 3% in women(PRIMATESTA and GOLDACRE, 2018). We have shown, as have others, that the prevalence of groin hernia in men is around 10% (Löfgren *et al.*, 2014)(Ohene-Yeboah *et al.*, 2016)(Abramson *et al.*, 1978). The prevalence of groin hernia in women has never been verified by epidemiological surveys including clinical examination(PRIMATESTA and GOLDACRE, 2018) (Patel *et al.*, 2014).

In high income settings women account for less than 10% of all adult groin hernia patients (Nilsson *et al.*, 2011). In some low income settings, however, women constitute up to 40% of patients undergoing hernia surgery (Löfgren *et al.*, 2014). Therefore, it is reasonable to assume that 5-10% groin hernia patients worldwide are women. This translates into 10-20 million women living with groin hernia and 1-2 million being operated for this condition each year. In addition, women with groin hernias are more often operated on as emergencies than men and face higher risks of adverse events including death (Nilsson *et al.*, 2011)(Nilsson, Stylianidis, Haapamäki, *et al.*, 2007). In resource constrained countries, mortality associated with emergency repair of strangulated hernia can be as high as 40% (Mbah, 2007). Watchful waiting is

not recommended in women due to the higher risk of incarceration and strangulation (M P Simons *et al.*, 2009).

It is well established that anterior mesh repair according to Lichtenstein is the open method of choice in men with groin hernia (Scott *et al.*, 2002). In women on the other hand, this surgical approach is a risk factor for recurrence (Burcharth *et al.*, 2014). In Sweden, over 40% of women re-operated after primary inguinal hernia repair were found to have femoral hernias (Koch *et al.*, 2005), and femoral hernias occur earlier meaning that they are overlooked at the primary operation. In high income settings, a pre-peritoneal endoscopic or open approach is recommended in women as both inguinal and femoral hernias can be repaired that way (M P Simons *et al.*, 2009). Endoscopic hernia repair is more costly and resource demanding than open hernia repair. Therefore, it will not be available to most patients in low and middle income countries within a foreseeable future and therefore it cannot be recommended in these settings. Open pre-peritoneal technique with mesh is difficult to master and therefore results are very dependent on the individual surgeon posing a substantial risk of recurrence (Koch *et al.*, 2005).

In Uganda, sutured techniques are the commonly used methods for groin hernia repair both in men and in women (manuscript). In women, a femoral hernia should be always excluded by laparoscopy or by open exploration of the pre- peritoneal space(Burcharth *et al.*, 2015).This ensures that femoral hernias are not overlooked. The suture methods used in inguinal hernia repair like the Shouldice and the Modified Bassini method do not recommend groin exploration for femoral hernias(Sachs, Damm and Encke, 1997). If a surgeon is operating on an inguinal or a femoral hernia that will be the focus of the operation. The infra inguinal approach has minimal access to the femoral canal allowing for recurrence of groin hernias in women. A safe and effective open technique which allows for exploration of both the inguinal and the femoral canal and that can be mastered by medical officers even in rural settings, is desired. This would have the potential to improve outcomes after groin hernia surgery in women in Uganda and other settings with limited financial and human resources.

8. Methodology

8.1. Study design

This is a parallel two arm double blinded randomized controlled trial. It is two arms because we have a control arm that will be treated with the open anterior mesh method and an intervention group that will be treated with the modified open anterior mesh method for a groin hernia. The study is double blinded because the principle investigator does not know the study arm of each of the participants and he will not take part in the surgical operations. Secondly the participant does not know which method has been used to treat the groin hernia.

8.2. Allocation ratio to treatment

The participants will be randomized into two arms, the control arm and the intervention arm. The control arm will have 220 participants and the intervention arm will have 220 participants. This gives a ratio of 1:1 between the control and the intervention arm.

8.3. Surgical methods and materials

The aim is to perform all procedures under local anaesthesia and as day case surgeries. Conversion to general or spinal anaesthesia may be required if there is excessive patient discomfort or pain.

Prior to starting of the study, the participating surgeons will operate an estimated 50 cases together to ensure that all surgeons are operating using the exact same technique. The planned number of surgeons is 10 (5 Ugandan and 5 International). A low-weight, commercial mesh made of polypropylene will be used in all patients.

For all participants, skin preparation will be done using povidone iodine; local anaesthesia will be constituted by an equal mix of lidocaine (10mg per milliter) and ropivacaine (7.5mg per ml). A prophylactic oral antibiotic of 1.5g of flucloxacillin will be administered one hour before surgery. For those who may have penicillin allergy, clindamycin, 900 mg will be administered 1 hour before surgery. One dose of 1 gram of paracetamol will be administered together with the antibiotics.

8.4. Description of intervention for each study arm

The two interventions for this study are a) the open anterior mesh repair (control group) and b) the modified open anterior mesh repair (the intervention group).

8.4a –The open anterior mesh repair

The open anterior mesh repair is done using the following approach. The inguinal canal is opened; the round ligament is identified and isolated. Do not excise the round ligament. The hernia sac is then identified and isolated. If an indirect sac is identified, it is opened to identify the contents. If contents are present, they are reduced; the sac is twisted until the turns reach the neck at the internal ring, this reduces the contents in the sac further into the peritoneal cavity. The sac is transfixed as proximal as possible and the stump is divided 1cm distal to the transfixing suture. A direct sac is inverted with a single absorbable invaginating suture. A sheet of prosthetic mesh measuring 5cm by 10 cm will be fashioned. The lower edge is sutured by a continuous nylon 2.0 suture, which secures the mesh medially to the lacunar ligament and then proceeds laterally along the inguinal ligament beyond the internal ring. The superior edge of the mesh is loosely secured to the internal oblique and the conjoint tendon with interrupted nylon 2.0 sutures. Laterally, the mesh is secured with interrupted nylon 2.0 to the inguinal ligament lateral to the inguinal ring, the internal oblique and the conjoint tendon. The external oblique will be repaired with a continuous absorbable vicryl 0. Interrupted skin sutures will be used to repair the skin.

8.4b The modified open anterior mesh repair for a groin hernia

The modified open anterior mesh repair method is performed using the following approach. The inguinal canal is opened; the round ligament is identified and isolated. Do not excise the round ligament. The hernia sac is then identified and isolated. If an indirect sac is identified, it is opened to identify the contents. If contents are present, they are reduced; the sac is twisted until the turns reach the neck at the internal ring, this reduces the contents in the sac further into the peritoneal cavity. The sac is transfixed as proximal as possible and the stump is divided 1cm distal to the transfixing suture. A direct sac is inverted with a single absorbable invaginating suture. The medial aspect of the transversalis fascia is opened in order to allow for exploration of the femoral canal. A thin part of a low weight mesh is extended into the

area to cover the femoral canal where a femoral hernia may arise. It is sutured to the inguinal ligament of cooper (pectineal ligament, using non absorbable suture nylon 2.0. The lower edge is sutured by a continuous nylon 2.0 suture, which secures the mesh medially to the lacunar ligament and then proceeds laterally along the inguinal ligament beyond the internal ring. The superior edge of the mesh is loosely secured to the internal oblique and the conjoint tendon with interrupted nylon 2.0 sutures. Laterally, the mesh is secured with continuous nylon 2.0 to the inguinal ligament lateral to the inguinal ring, the internal oblique and the conjoint tendon. The external oblique is repaired with continuous vicryl 0. Interrupted skin sutures will be used to repair the skin.

8.5. Postoperative management

Immediately after operation, the participants receive the next dose of oral analgesia (paracetamol and ibuprofen). All patients will receive oral paracetamol 1gm every 6hours for the next 5 days as well as ibuprofen 400 mg every 8 hours for 5 days. When the pain subsides, the frequency of using pain medication will reduce and most will not need to use analgesia for more than 5 days.

At least two hours after operation, a medical doctor will assess the patients to determine if they can be discharged from the hospital. Those unable to go home will be observed in the hospital until they are fit to leave. Patients operated late in the day will also stay overnight depending on travel distance to go home.

All patients will be instructed to keep the dressing for 7 days. On the 7^{th} day, they will remove the dressing by themselves. Prior to discharge from the hospital, all patients will receive written and oral information about what to expect during the recovery period, warning signs and a scheduled date and time for follow up. The patients will be given a phone number to contact the study team if questions or complications arise.

8.6 Follow up

Follow up will take place for all patients after 14 days, 1 year and 3 years. The follow up will consist of interviews performed by the research assistants using the study tools. Thereafter, a physical examination will be performed by a physician. At the 14 days follow up, the sutures will also be removed. Patients will mostly be followed up

at the point of inclusion into the study. If necessary, patients may also be seen from other sites including their homes.

8.7. Study areas

The study will be carried out in 11 hospitals in Uganda some of which are Regional Referral Hospitals and others are General Hospitals provided they have an operating theatre with the Uganda Ministry of Health Standards. The hospitals are Mubende Regional Referral Hospital, Hoima Regional Referral Hospital, Jinja Regional Referral Hospital, Iganga Hospital, Buluba Hospital, Kitovu Hospital, Tororo Hospital, Kitgum Hospital, Lacor Hospital, Arua Regional Referral Hospital and Kamuli Mission Hospital. These hospitals have been selected depending on convenience to the research team.

8.8. Study population

8.8a. Inclusion criteria:

Adult women 18 years and above,(this is the age of consent and below 15yrs of age the body is still growing making it inappropriate to use mesh repair) with primary, reducible groin hernia, ASA class 1 and 2(Sankar *et al.*, 2014) and with ability to give a written informed consent.

8.8b. Exclusion criteria

Recurrent hernia, incarcerated groin hernia requiring emergency operation, known coagulopathy (including medically induced, but not including daily usage of low dose aspirin), known pregnancy, obvious alcohol or substance abuse. Only obvious drug and alcohol abuse is an exclusion criterion. Signs can range between the individual being drunk, smelling of alcohol and being in poor general condition. For the latter, it can be expected that they will belong to ASA class 3 or higher which in itself is an exclusion criteria. Lab tests will not be used to diagnose drug or alcohol abuse.

8.9. Sample size and calculation

This trial has a superiority design. With 80% power, and 5% precision rate, and an expected success in the intervention arm of 99% after one year and 94% in the control arm, a sample size of 418 study participants is required. To compensate for un expected loss to follow up of 5%, 440 patients will be enrolled into the study. The

calculation is based on the formula below. The calculation was done using the online tool “sealed envelope Ltd 2012”.

$$n = f(\alpha/2, \beta) \times [p_1 \times (100 - p_1) + p_2 \times (100 - p_2)] / (p_2 - p_1)^2$$

$$f(\alpha, \beta) = [\Phi^{-1}(\alpha) + \Phi^{-1}(\beta)]^2$$

p1 and p2 are proportion of expected success rate in control and intervention group respectively, β=power, α=significance level, Φ^{-1} is the cumulative distribution function of a standardised normal deviate.

8.10. Sampling procedures

Mobilization will be done over radio and through raising awareness by the local leadership as well as through the study hospitals and other health facilities in the vicinity of the study hospitals. Potential study participants will present to the recruitment site, most commonly the study hospital. There they will be informed about the study and will get the chance to ask question in group and individually. The potential study participants will be assessed for eligibility to be included into the study. Those who fulfill the criteria or those where the physical examination is inconclusive will receive a date for when they should present at the study hospital.

That day, the following will take place:

a. Informed consent
b. Interviews using study questionnaires
c. Physical examination to confirm that inclusion criteria are met
d. Ultrasonography of the groins will be done for all study participants. Individuals where the physical examination has been inconclusive will be offered ultrasonography before inclusion into the study as individuals who do not have a groin hernia are not eligible study participants.

Those who meet the eligibility criteria and who have given their consent to be part of the study will remain in the hospital for operation on the following day. A theatre list for the following day’s operations will be generated. On the day of the operation,

patients will be distributed consecutively to the surgeons according to the predetermined theatre list.

8.11. Randomization method

Randomization for the surgical method to be applied will be done after the surgeon and the patient he or she is going to operate on have entered the operating room. A computer based program will be used to randomize the sequence of treatment groups in blocks of four and six. The allocation ratio between the study arms will be 1:1. After randomization, the surgeon will be informed which method to use. If a femoral hernia is detected intra operatively in a patient randomized to the control group (study arm A) the patients will cross over to the intervention group (study arm B). The physicians doing the follow up of the patients will not take part in randomization or the operations. The patients will not be informed which study arm they have been allocated to. Thus the patients and the physicians doing the follow up will be blinded to the treatment arm of the patient in this study.

8.12. Blinding mechanism

The physicians doing the follow up of the patients will not take part in randomization or the operations. The patients will not be informed which study arm they have been allocated to. Thus, the patients and the physicians doing the follow up will be blinded to the treatment arm of the patient in this study.

8.13. Assessment of safety

The WHO checklist for safe surgery (appendix 12) will be used in the operating room. The patients will be monitored in the hospital after the operation for 2 hours. This is a normal duration of postoperative monitoring for elective day case surgery. Major bleeding or complications with severe pain will be detected within that time interval. Only patients who are fit to go home will be discharged from the hospital. The patients will receive oral and written information about the time after the procedure, including expected recovery and warning signs. The patients will be given a phone number to the principal investigator which they can call if needed. If a complication has occurred, they will receive instructions on what to do. An extra assessment will be

done if that is required.

8.14. Adverse events reporting

Adverse events will be investigated and reported to the Principal Investigator and Ms Harriet Chemusto chairperson MUREC. An adverse assessment and records tool will be used to record and report all adverse events among the study participants (appendix 13).

8.15. Data safety and monitoring plan

Each patient will be given a study number and the data will be kept in a locked box during field work, the key with the Principle Investigator. After data entry and scanning of forms containing only the study number, the forms will be delivered to Mildmay Uganda for storage for 10 years.

8.16. Quality assurance

The Principal Investigator is responsible for the collection and quality of the data. After each day, study forms will be reviewed and missing information will be retrieved. Correction of errors is the responsibility of the Principle Investigator.

8.17. Funding source

The study is funded through grants for development studies and awarded by the Swedish Research Council. The Swedish Research Council is Sweden's largest governmental research funding body, and supports research of the highest quality within all scientific fields. For further details, please see: https://www.vr.se/english. The same grant has also been used to fund hernia research in Ghana and in Sierra Leone. The grant was awarded to Prof Andreas Wladis, one of the co-investigators and is managed by Linköping University

9. Study variables

9.1. Primary endpoints:

Postoperative complications are excessive pain of scores 8,9 and 10 using the Visual Analogue Scale, chronic pain, hematoma/bleeding, infection, seroma formation, urinary retention, and others judged to be so at two weeks and hernia recurrence after one and three years. These end points will be used to determine the safety and effectiveness of both methods which will be compared between both arms of the study.

9.2. Secondary endpoints:

Patient satisfaction and quality of life at one and three years compared to before the surgery. Accuracy of groin sonography for female groin hernias will be determined. Cost and cost effectiveness will be calculated based on outcomes at one year follow up.

Cost-effectiveness will be expressed as cost in USD per DALY averted and QALY gained. These will be calculated as follows:

i. Costs of the interventions. This will include cost of medicines and materials, staff costs, capital costs and overhead costs (appendix 14)

ii. DALYs will be calculated using the following formula:

DALY = YLD + YLL
YLD = DW X remaining life expectancy at the time of surgery
YLL = risk of early death without surgery X remaining life expectancy at time of surgery

The results from the Inguinal Pain Questionnaire which is part of the interview tools will be translated into three levels of abdominopelvic problem (mild, moderate and severe) according to the global burden of disease study. The values for the most recent version of the Global Burden of Disease Study at the time of data analysis will be used. Remaining life expectancy at the time of the surgery will be retrieved from the WHO Life Table for Uganda. In the lack of information on the risk of incarceration of groin hernia in women, the same value as for men will be used but a sensitivity analysis will also be used, where the expected risk of death is modulated.

DALYs averted will be calculated using the difference of YLD and YLL between the preoperative assessment and the one year follow up, multiplied with the remaining life expectancy at the time of the operation.

iii. QALYs will be calculated using the following formula:

QALY = index value X remaining life expectancy at time of surgery

The results from the EQ5D form that is part of the interview tools will be translated into index values using the EQ5D Index Value Translator from the EuroQol group website. Remaining life expectancy at the time of the surgery will be retrieved from the WHO Life Table for Uganda. QALYs gained will thereafter be calculated using the difference in index value before and 1 year after surgery multiplied by the remaining life expectancy at the time of surgery

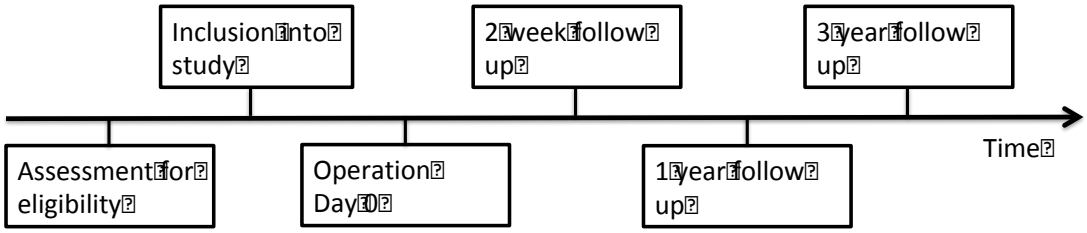
These methods were used in a previous study on groin hernia surgery in men in Uganda and we are also using it for cost effectiveness analysis in our trials in Ghana and Sierra Leone (Löfgren *et al.*, 2017). Using the same method will enable comparison between countries.

We expect that the modified version of the anterior mesh repair will be superior to the original anterior mesh repair in terms of recurrence rate. As the modified version involves surgery close to sensitive structures, the risk of particularly hematoma could be increased. We expect both methods to be highly cost effective but that the modified version will be more cost effective as we expect that the recurrence rate in this group will be lower than in the control group.

10. Data collection

Data will be collected at different stages of the study by the responsible team. Pre – operative data will be collected by the Principle Investigator and research assistants, intra operative data will be collected by the surgeon operating on the patient. The immediate post operative data and ongoing follow up data will be collected by the Principle Investigator and the research assistants. Timeline for study activities is presented in Figure 3 below.

10.1. Figure 3. Timeline for study activities involving patients



11. Recruitment

11.1. Participant recruitment

Participants will be mobilized using radios, village health teams and the local leaders. Radio stations will be given an approved announcement that will call upon women with groin swellings to come to the respective hospitals gazetted as a study site. All those that fulfill the inclusion criteria will fill a written consent form after a full explanation by the Principle investigator. The recruited participants will receive a general and specific examination by the Principle Investigator. Both those with clinical groin hernias and those with unequivocal clinical findings at examination will have groin sonography performed by a physician. Those with clinically and sonographically confirmed diagnosis will be randomized into the study.

11.2 Training of research assistants

Field assistants will be recruited to perform interviews with the patients at recruitment and follow up. The Principle Investigator is responsible for this training. The field assistants will not be working on their own but will be supervised by the Principle Investigator or another doctor involved in recruitment and follow up.

11.3 Tools

The tools consist of consent forms, contact information, questionnaires and forms for physical examination (See appendix 1 to 14). Answers have been coded, when possible.

11.4 Pre-testing

The tools were used previously in a double blinded randomised clinical trial of a low cost mesh in groin hernia repairs in men. They will be updated so that gender specific questions relate to women instead of men. Additional pre-testing is not necessary.

11. 5 Field editing of data

After each day, the questionnaires filled will be reviewed. This will enable to edit data for correctness and accuracy. Any inconsistent information will be discussed with the field assistants for correction.

11.6 Missing data

Any missing data will be discussed with the field assistants for filling and correction. Some information may have to be verified with a patient over the phone or at the next scheduled appointment.

11. 7 Data management and analysis

The data will be managed by observing strict collection protocols, entry, cleaning and analysis. The data will be stored securely in both hard and soft copies.

11.8 Data entry and cleaning

The Principal Investigator is responsible for the data entry and cleaning of the data. He will do large parts of it himself but may delegate this task to others in the research team, potentially including medical students. External staff for data entry will not be used. Data will be entered into excel spread sheets

11.9 Analysis plan and dissemination plan

Data analysis will be performed using primarily Excel and SPSS. Counts will be presented as numbers and per cent and comparison of binary values will be done using chi square test, Fischer exact test or an exact binomial test as appropriate. Continuous data will be presented as mean and standard deviation and analysis will be done using students t-test. Absolute difference between the study groups for the primary and secondary endpoints will be calculated and presented with 95% confidence intervals. A difference of more than 5 percentage points for the primary endpoint (recurrence) is considered clinically relevant. A p-value of 0.05 is considered statistically significant.

The PI is responsible for the quality control. The findings of the study will be disseminated through presentations in local and international conferences as well as publications in peer reviewed journals. The dissemination strategy also involves ministries of health, international organisations, policy makers and funders of global health initiatives. Information about the results to the study participants will be

delivered at the time of the follow up (1 year and 3 years). A report will be made available to study participants and others through the study hospitals.

12. Ethical considerations

Ethical clearance has been obtained from the Mildmay Uganda Research and Ethics Committee accredited by the Uganda National Council of Science and Technology. Letters of administrative clearance will be obtained from the respective hospitals where the operations will be conducted before submission to Uganda National Council of Science and Technology.

Patients will receive oral and written information about the study in their local language. They will be included into the study after having given written consent. In case they cannot write, they will thumb print the consent form.

Confidentiality is assured for the study participants. Questionnaires will be stored at the Mildmay Uganda Research office. De-identification of data will be done at data entry. No one part from the research team and field assistants will be involved in the management of the data.

The main benefits to the study participants are receiving a hernia repair at no cost, close follow up and attending to any complications at no cost to the patient. There are always risks associated with surgery but these are not elevated by the present study. The potential risks expected include postoperative complications that are normally seen after groin hernia surgery. These include post operative bleeding with hematoma formation, seroma formation and wound infection. Long term complications include chronic pain and hernia recurrence. Sterility practices and the WHO surgical safety checklist will be used to reduce risks associated with surgery. The WHO surgical safety checklist is attached as appendix 12. At discharge, the patients will receive oral and written information about the post operative period. This includes what to expect and warning signs for when to contact the study team. They will be given a contact number of a doctor at the hospital where they had the operation and the principal investigator to call. If the patient needs to travel to hospital but cannot reach the hospital in a short time we shall facilitate her to travel. An additional visit to or by the study team may be carried out. Need for reoperation or surgical interventions for complications are very rare. Most complications will be handled conservatively with antibiotics or analgesics. In situations of hernia recurrence, the participant will be offered a re-operation by a surgeon experienced in this, at no cost to the patient.

References

Abramson, J. H. *et al.* (1978) 'The epidemiology of inguinal hernia. A survey in western Jerusalem', *Journal of Epidemiology and Community Health*, 32(1), pp. 59–67.

Alkire, B. C. *et al.* (2015) 'Global economic consequences of selected surgical diseases: a modelling study', *The Lancet. Global Health*, 3 Suppl 2, pp. S21-27. doi: 10.1016/S2214-109X(15)70088-4.

Bae, J. Y., Groen, R. S. and Kushner, A. L. (2011) 'Surgery as a public health intervention: common misconceptions versus the truth', *Bulletin of the World Health Organization*, 89(6), p. 394. doi: 10.2471/BLT.11.088229.

Beard, J. H. *et al.* (2015) 'Hernia and Hydrocele', in Debas, H. T. et al. (eds) *Essential Surgery: Disease Control Priorities, Third Edition (Volume 1)*. Washington (DC): The International Bank for Reconstruction and Development / The World Bank. Available at: http://www.ncbi.nlm.nih.gov/books/NBK333501/ (Accessed: 29 April 2018).

Bickler, S. W. and Spiegel, D. A. (2008) 'Global surgery—defining a research agenda', *The Lancet*, 372(9633), pp. 90–92. doi: 10.1016/S0140-6736(08)60924-1.

Burcharth, J. *et al.* (2014) 'Direct inguinal hernias and anterior surgical approach are risk factors for female inguinal hernia recurrences', *Langenbeck's Archives of Surgery*, 399(1), pp. 71–76. doi: 10.1007/s00423-013-1124-z.

Burcharth, J. *et al.* (2015) 'Patient-Related Risk Factors for Recurrence After Inguinal Hernia Repair: A Systematic Review and Meta-Analysis of Observational Studies', *Surgical Innovation*, 22(3), pp. 303–317. doi: 10.1177/1553350614552731.

Debas, H. T. *et al.* (2006) 'Surgery', in Jamison, D. T. et al. (eds) *Disease Control Priorities in Developing Countries*. 2nd edn. Washington (DC): World Bank. Available at: http://www.ncbi.nlm.nih.gov/books/NBK11719/ (Accessed: 27 October 2013).

Groen, R. S. *et al.* (2012) 'Untreated surgical conditions in Sierra Leone: a cluster randomised, cross-sectional, countrywide survey', *Lancet*, 380(9847), pp. 1082–1087. doi: 10.1016/S0140-6736(12)61081-2.

Kark, A. E. and Kurzer, M. (2008) 'Groin hernias in women', *Hernia*, 12(3), pp. 267–270. doi: 10.1007/s10029-007-0330-4.

Koch, A. *et al.* (2005) 'Prospective evaluation of 6895 groin hernia repairs in women', *British Journal of Surgery*, 92(12), pp. 1553–1558. doi: 10.1002/bjs.5156.

Löfgren, J. *et al.* (2014) 'Prevalence of treated and untreated groin hernia in eastern Uganda', *The British Journal of Surgery*, 101(6), pp. 728–734. doi: 10.1002/bjs.9457.

Löfgren, J. *et al.* (2017) 'Cost-effectiveness of groin hernia repair from a randomized clinical trial comparing commercial versus low-cost mesh in a low-income country', *The British Journal of Surgery*. doi: 10.1002/bjs.10483.

Manuscript. Groin hernia surgery in Uganda. A hospital based survey on the volumes and practices.

Mbah, N. (2007) 'Morbidity and mortality associated with inguinal hernia in Northwestern Nigeria', *West African Journal of Medicine*, 26(4), pp. 288–292.

Meara, J. G. *et al.* (2015) 'Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development', *Lancet*. doi: 10.1016/S0140-6736(15)60160-X.

Nilsson, H., Stylianidis, G., Haapam??ki, M., *et al.* (2007) 'Mortality After Groin Hernia Surgery':, *Annals of Surgery*, 245(4), pp. 656–660. doi: 10.1097/01.sla.0000251364.32698.4b.

Nilsson, H., Stylianidis, G., Haapamäki, M., *et al.* (2007) 'Mortality after groin hernia surgery', *Annals of Surgery*, 245(4), pp. 656–660. doi: 10.1097/01.sla.0000251364.32698.4b.

Nilsson, H. *et al.* (2011) 'Mortality after groin hernia surgery: delay of treatment and cause of death', *Hernia: The Journal of Hernias and Abdominal Wall Surgery*, 15(3), pp. 301–307. doi: 10.1007/s10029-011-0782-4.

Nilsson, H., Holmberg, H. and Nordin, P. (2017) 'Groin hernia repair in women – A nationwide register study', *The American Journal of Surgery*. doi: 10.1016/j.amjsurg.2017.07.027.

Ohene-Yeboah, M. *et al.* (2016) 'Prevalence of Inguinal Hernia in Adult Men in the Ashanti Region of Ghana', *World Journal of Surgery*, 40(4), pp. 806–812. doi: 10.1007/s00268-015-3335-7.

Patel, H. D. *et al.* (2014) 'An estimate of hernia prevalence in Sierra Leone from a nationwide community survey', *Hernia: The Journal of Hernias and Abdominal Wall Surgery*, 18(2), pp. 297–303. doi: 10.1007/s10029-013-1179-3.

Perry, C. P. and Echeverri, J. D. V. (2006) 'Hernias as a Cause of Chronic Pelvic Pain in Women', p. 4.

PRIMATESTA, P. and GOLDACRE, M. J. (2018) 'Inguinal Hernia Repair: Incidence of Elective and Emergency Surgery, Readmission and Mortality', *INTERNATIONAL JOURNAL OF EPIDEMIOLOGY*, p. 5.

Ruhl, C. E. and Everhart, J. E. (2007) 'Risk Factors for Inguinal Hernia among Adults in the US Population', *American Journal of Epidemiology*, 165(10), pp. 1154–1161. doi: 10.1093/aje/kwm011.

Sachs, M., Damm, M. and Encke, A. (1997) 'Historical evolution of inguinal hernia repair', *World Journal of Surgery*, 21(2), pp. 218–223. doi: 10.1007/s002689900220.

Sankar, A. *et al.* (2014) 'Reliability of the American Society of Anesthesiologists physical status scale in clinical practice', *British Journal of Anaesthesia*, 113(3), pp. 424–432. doi: 10.1093/bja/aeu100.

Scott, N. W. *et al.* (2002) 'Open mesh versus non-mesh for repair of femoral and inguinal hernia', *The Cochrane Database of Systematic Reviews*, (4), p. CD002197. doi: 10.1002/14651858.CD002197.

Simons, M P *et al.* (2009) 'European Hernia Society guidelines on the treatment of inguinal hernia in adult patients', *Hernia: the journal of hernias and abdominal wall surgery*, 13(4), pp. 343–403. doi: 10.1007/s10029-009-0529-7.

Simons, M. P. *et al.* (2009) 'European Hernia Society guidelines on the treatment of inguinal hernia in adult patients', *Hernia*, 13(4), pp. 343–403. doi: 10.1007/s10029-009-0529-7.

The HerniaSurge Group (2018) 'International guidelines for groin hernia management', *Hernia*, 22(1), pp. 1–165. doi: 10.1007/s10029-017-1668-x.

Weiser, T. G. *et al.* (2008) 'An estimation of the global volume of surgery: a modelling strategy based on available data', *Lancet*, 372(9633), pp. 139–144. doi: 10.1016/S0140-6736(08)60878-8.

APPENDICES

Patient study number

Appendix 1. Consent form(for participant)

Introduction: My name is ……., and I am part of the team conducting a study entitled open anterior mesh repair versus modified open anterior mesh repair for groin hernia in women. A double blinded randomized controlled trial. This study has been approved by an accredited research and ethics committee (Mildmay Uganda Research and Ethics Committee)**.**

Purpose: Inguinal hernia is a common condition worldwide. Among men, the prevalence was almost 10% in a previous study. The surgery method that is commonly used to treat inguinal hernia in men uses a mesh to reinforce the abdominal wall and reduce the risk of recurrence. Very few studies evaluating the best surgical technique in women have been done but it is clear that the same method normally used in men is not optimal in women. In a previous study that we conducted on hernia surgery in men, we found that a low cost mesh was safe and effective. In this study we will evaluate if this mesh can be used also in women using a technique modified for female patients. We will compare this method with current mesh techniques that involve mesh.

Research procedure: We will recruit 440 women with groin hernia from the catchment populations of Mubende Regional Referral Hospital, Iganga hospital Hoima Regional Referral Hospital, Jinja Regional Referral Hospital, Buluba Hospital, Kitovu Hospital, Tororo Hospital, Kitgum Hospital, Lacor Hospital, Arua Regional Referral Hospital and Kamuli Mission Hospital. Half of the patients will be operated using the current open anterior mesh technique and the other half will be operated using the modified open anterior mesh technique which is under investigation. The patients will not know which method was used. The surgeries will be performed by surgeons under local anaesthesia. This means that the patient will be awake during the surgery but will not feel pain. The operation will take between 60 to 120 minutes. After the surgery, the patient is able to move freely and it is safe to go home the same day. After 2 weeks, after one year and after 3 years, the patient will be interviewed and thereafter examined by a medical doctor to assess the results of the surgery. The participants will get a feed back on the progress and findings of the study

Potential benefits from this study: You will receive surgery for your hernia free of charge. You will receive UGX 20,000 to facilitate your transport on every visit to the study site to participate in the study, i.e., pre –enrolment, two weeks post enrolment when you turn up for review, one year post enrolment for the one year

review and 3 years post enrolment for the 3 year review. If any complications occur, and you cannot reach the hospital in a short time, we will facilitate you to travel, and for all complications we will provide you with correct and effective treatment. You will receive follow up after 2 weeks and one year so that potential complications can be found and treated in time.

Potential harm from this study: All surgical interventions have some risks. Some patients have pain after the surgery and a small number will have chronic pain. Some may have bleeding from the wound or a haematoma, There is a risk of infection with pus discharge at the operation site. In some patients the hernia may recur. In case any complications occur, inform the Principle Investigator and travel back immediately to the study site for assistance. The risk for these complications will be reduced to a minimum through safety measures taken by the study team. A few patients may have recurrence of the hernia. We will provide a reoperation if that occurs.

Voluntary participation: Participation in this study is voluntary. If you choose to take part, I will first ask you to sign or finger print this document to verify your consent to participate. Thereafter, I will ask some questions about your health in general and your inguinal hernia in particular. Together, we will decide a date when you will come to the hospital nearest to you for an operation. The procedure will be performed the day after. A doctor will meet you for a medical control 2 weeks after the surgery, one year after the surgery and three years after surgery.

Confidentiality and autonomy: The information that you give us will be kept safely so that no one apart from the investigators have access to it. All data will be de-identified so that your name will not appear in the analysis or any resulting publications. If you have any questions about the study, please ask me. Also (PIs name and phone number) can be contacted for further questions. It is your decision to participate in the study and you are free to stop taking part in the study at any time without any consequences or penalty.

Questions regarding the rights of participants or any complaints about the research can be directed to Ms. Chemusto Harriet, phone number 0392-174-236, the chairperson of Mildmay Uganda Research and Ethics Committee.

Acceptance: Before we proceed with the interview, I would like to seek your permission. Do you consent to participate in the study?

I have been fully explained about this study and understand its purpose and objectives. I understand the details and have been informed about the requirements of the study. My questions have been answered satisfactory. I hereby agree to participate in the study.

Name of participant ……

Signature of participant _____

Date_____

Thumb print of respondent ----------

Witness's signature if participant is illiterate

……..

Name of person obtaining the consent ……

Signature of person obtaining the consent _____

Date_____

Appendix 2

Participant contact information(for participant).

Patient study number

Filled in by _____

Date and place _____

A. Identification of the patient

1.Name:_____

2.Name of district_____

3. Name of county……...

4. Name of subcounty…….

5. Name of parish……

3.Village name_____

4.Mobile phone number 1_____

5. Mobile phone number 2 _____

6. Mobile phone number 3 _____

7.Name of Next of kin……..

8. Relationship. ……

9. Phone number of next of kin……

10.Local chairman_____

11. Phone number of local chairman_____

12.Occupation_____

13. Place of work (if any) _____

Patient study number

14. Additional contact information

_____

_____

_____

Appendix 3: The Medical History Form(for participant)

Patient study number

Filled in by _____

Date and place _____

A. Identification of the patient

1.Name:_____

2.Name of district_____

3.Villagename_____

4.Mobile phone number 1_____

5. Mobile phone number 2 _____

6. Mobile phone number 3 _____

7.Local chairman_____

8. Phone number of local chairman_____

9.Occupation_____

10. Place of work (if any) _____

11. Additional contact information

_____

_____

_____

12.Emyaka Age in years ☐

13. Ofuwa sigara

Smoker 1=Yes, 2=No, 3=Stopped ☐

Patient study number

14a. Are you pregnant? **Olhi mabunda?**

1=yes, 2=no, 3=it is possible, 4=other

14b. If yes at question 14a, refer the paient to the doctor.

15. Do you have any chronic diseases?

Olinha obulwaile obulwirewo?

1=yes 2=no

16. If yes, which diseases?

Oba ihi? bulwaire ki?

_____

_____

17. Do you have diabetes?

Olinha obulwaire bwa sukaali?

1=yes, 2=no, 3= do not know, 4=other (specify).....

18. Do you have a cardiac problem?

Olinha obulwaire bw'omutima?

1=yes, 2=no, 3= do not know, 4=other (specify).....

.....

19. Do you have any medical condition which affects your lungs?

Olinha obulwaire bwona bwona mu mamawuwe?

1=yes, 2=no, 3= do not know, 4=other

(specify).....

20. Do you have any coagulation disorder?

Olinha obuzibu nti bwe wabawo ekikusaze oba omusaayi okwidha tegulekerawo mangu?

1=yes, 2=no, 3= do not know

Patient study number

21. Do you have any ongoing infectious disease?

Olinha obulwaire obuva mu buwuuka ng'akawuuka akaleeta sirimu, hepatitis oba TB?

1=yes, 2=no, 3= do not know .....

22. If yes, which disease?
Oba yi, bulwaire ki?
1=Hepatitis B, 2=hepatitis C, 3= HIV, 4=TB, 5=other.....

23. Do you take any medication regularly?

Olinha amakerenda gomira buli lunaku?

1=yes, 2=no, 3= other .....

24. If yes, which medicine(s)? **Oba yi, makerenda ki?**

1_____

2_____

3_____

4_____

25.Have you ever had surgery?

Bakulongoosa ku?1=yes, 2=no, 3= do not know, 4=other (specify).....

26. If yes, when was it? **Oba yi? Bakulongosaali?**

1= A month ago. 2= More than a month ago? 3= do not know, 4=other (specify).....

27. If yes, which condition was operated?

Oba yi? Bakulongosaaki?

1=groin hernia, 2=do not know, 3=other (specify).....

28. Bwekiba yi 14, bakulongoseza gha?

If yes at question 14, where was the procedure performed

Patient study number

1=Hospital, 2=Other public health facility, 3=Private clinic, 4= Do not know,

5=Other location (specify) .....

29. Oliku n'obuzimbu mu limu oba mu maago gombi?

Do you have a swelling in any or both of your groins?

1=No, 2=Right side, 3=Left side, 4=Both sides, 5=other (Specify).....

For 30, put an (x) in the appropriate choice.

30. Do you feel pain in any or both of your groins?
Owuliraku obulumi bwonabwona mu limu oba mu maago gombi ?

	Right	Left
1. No pain Wazila bulumi.	□	□
2. Pain present but could easily be ignored. Obulumi buliwo aye busoboka okuguminkirizibwa.	□	□
3. Pain present, could not be ignored, but did not interfere with everyday activities. Obulumi buliwo,tibuguminkirizibwa aye tibundobela kukola milimo edha bulidho.	□	□
4. Pain present, could not be ignored, and interfered with concentration on chores and daily activities. Obulumi buliwo,tibuguminkirizibwa tisobola kwisa isira kumilimo dha bulido.	□	□
5. Pain present, could not be ignored, and interfered with most activities. Obulumi buliwo, tibuguminkilizibwa, bunemesa okukola emilimo egisinga bungi.	□	□
6. Pain present, could not be ignored, and necessitated bed rest. Obulumi buliwo ,tibuguminkilizibwa bumpaliliza kuwumula kukitanda.	□	□

Participant number

Patient study number

7. Pain present, could not be ignored, prompt medical advice sought. □ □
   Obulumi buliwo, tibuguminkilizibwa bumpaliliza kunonya magezi okuva ewomusawo mangu.

31. For how long have you had the pain in the groin?

    Omaze eibangaki ng'owulira obulumi ? ☐

    1=0-6 months, 2=more than 6 months, 3=Don't know

32. Have you had any episodes of severe pain in the groin?

    Walikuku n'ebiseera wewawulira obulumi obwamani eihno?

    1=Yes, 2=No, 3=Dont know ☐

33. Additional information and comments

……

……

……

……

Appendix 4. Preoperative Physical Examination(for participant)

Patient study number

Filled in by _____

Date and place _____

Identification of the patient

1. Name _____

2. Age in years

Examination

3. Date of examination (dd/mm/yy)

4. Weight (kg)

5. Height (cm)

6. Blood pressure (mmHg/mmHg)

7. Pulse (BPM)

8. Respiratory rate (per minute)

9. Temperature (°C)

10. Heart 1=normal, 2=significant abnormality (specify)……

11. Lungs 1=normal, 2=significant abnormality (specify)

12. Abdomen.1= normal, 2=minor/moderate abnormality (specify

3=scar from previous surgery……

4=significant abnormality (specify)……..

13. Inguinal scar from a previous groin hernia repair

1.Yes 2.No 3. Do not know.

14. Location of inguinal scar *1=N/A, 2=Right side, 3=Left side, 4=Bilateral*

15. Left/right/bilateral *1=N/A, 2=Right side, 3=Left side, 4=Bilateral*

16. Reducible mass *1=N/A, 2=Yes, 3=No*

17. Clinical impression of the groin(s)

1=No groin hernia, 2=Obvious reducible inguinal hernia, 3=Obvous irreducible inguinal hernia,

4=Suspected groin inguinal hernia, 5= Femoral hernia, 7= Suspected Lymphadenitis, 8=Unknown,

10=Other .....

18. Ultrasound examination findings.

i. Groin hernia present?

a. Yes b. no

……

ii. What is the type of groin hernia?

a. Indirect groin hernia. b. direct groin hernia. c. femoral/not specified…….

iii. Size of sac

a. 1-3 cm b.3-5cm c. more than 5 cm

iv. Size of orifice in mm……

v. Bowel content?

a. yes b. no……

vi. Completely reducible?

a.yes b. no……

vii. Other groin sonography findings.

……

……

Patient study number

viii. Sonography examination performed by

……
…

19. ASA classification

1= A normal healthy patient, 2=A patient with mild systemic disease,

3=A patient with severe systemic disease,

4=A patient with severe systemic disease that is a constant threat to life,

5=A moribund patient who is not expected to survive without the operation.

20. Recommendation:

1=Herniorrhaphy, 2=No surgery indicated at present state,

3= Other.....

21. Does the patient meet the inclusion and exclusion criteria for the mesh study?

1=yes, 2=no

Inclusion criteria	***Exclusion criteria***
○ Woman ○ Age > 18 years ○ Reducible inguinal hernia ○ Primary inguinal hernia ○ Elective inguinal hernia ○ The patient accepts to participate ○ Ability to give informed consent	○ Recurrent hernia ○ Anticoagulant medication or coagulation abnormality ○ Drug abuse including alcohol with significant Physiological or mental consequences ○ ASA group 3 and above ○ Known pregnancy

22. Comments:

.....

.....

.....

.....

.....

Appendix 5. Intervention protocol (for participant)

Patient study number

Filled in by _____

Date and place _____

Identification of the patient

1. Name _____

2. Age in years | | |

Intervention

3. ISS status
1=Positive, 2=Negative, 3=UK | |

Remember to erase interpretation with a dark pen after filling!

4. Date of intervention (dd/mm/yy) | | | | | | |

5. Time that patient entered operation theatre | | hh | | | mm

6. Start of intervention (first incision) | | hh | | | min .

7. End of intervention (last stitch) hh | | | min

8. Time that patient left the operation theatre | | hh | | | min

9. Hernia type
1=medial, 2=lateral, 3=combined medial and lateral, 4=femoral hernia, 5 =no hernia identified,
5=other…… | |

Patient study number

10. Technique used

1= Lichtenstein technique, 2= modified mesh technique, 3= other…….

11. If local anaesthesia was not used or if it was combined with another anaesthetic method, state the reason (if necessary write on backside)

……
……
……

12. Complications during the operation? Specify.

1=Excessive bleeding, assess volume…… ml

2=Accidental damage to other tissue or organ

(specify)…….……

3=Injury of staff

(specify)……

4=Anaesthetic complications

(specify)…….……..

5=Other complication

(specify)……..

Theatre staff

13. Name of

surgeon……

14. Anesthesia method:
1=local, 2=IV General Anesthesia, 3=Inhalation General Anesthesia, 4=Spinal, 5=Other……..

15. Title of anesthetist/ position:
1=Self, 2=Anesthetic officer, 3=Other (specify)……

16. Additional information and comments

……

……

……

……

……

Appendix 6: Operation description for mesh repair method(for participant)

Patient study number

Please describe the procedure you have just performed, from start to end, by filling the following standard questions.

1. Local anesthesia given according to description
2. Skin incision
3. External fascia opened
4. Identification and management of inguinal nerves

	Identified	Isolated	Cut
Ilioinguinal nerve			
Genital branch of the genitofemoral nerve			
Iliohypogastric nerve			

5. Funicle isolated and opened

A. **Lateral hernia**

6. Hernia sack identified and isolated
7. Hernia sack opened
8. Contents of hernia sack. 1=yes, 2=no
9. If yes, 1=omentum, 2=small intestine, 3=large bowel, 4=other (Specify)……..
10. Hernia sack excised
11. Hernia sack invaginated
12. Hernia sack cut and distal part leave in situ
13. Medial aspect of transversalis fascia opened
14. Femoral canal explored for femoral hernia

Patient study number

15. Femoral hernia identified (Y/N)

16. Hernia sac excised

17. Hernia sac invaginated

Mesh cut to fit the patient

17. Slit for coverage of femoral canal cut

18. Mesh put in place. Slit sutured to Inguinal,

lacunar and pectineal ligament

19. Mesh sutured according to open anterior mesh method

20. Hemostasis checked

21. External fascia sutured

22. Interrupted skin sutures

23. Medial hernia

24. Hernia sack identified

25. Hernia sack invaginated by suturing

26. Medial aspect of transversalis fascia opened

27. Femoral canal explored for femoral hernia

28. Femoral hernia identified (Y/N)

29. Mesh cut to fit the patient

30. Slit for coverage of femoral canal cut

31. Mesh put in place. Slit sutured to inguinal

Lacunar and pectineal ligament.

32. Mesh sutured according to Lichtenstein method ⧉

33. Hemostasis checked ⧉

34. Mesh sutured according to Lichtenstein method ⧉

35. External fascia sutured ⧉

36. Interrupted sutures of the skin ⧉

37. No hernia sack identified (add comments below) ⧉

38. Additional information and comments

_____
_____
_____
_____

Appendix 7. Discharge form(for participant)

Patient study number

Filled in by

_____

Date and place (dd/mm/yy) | | | | | | |

_____

Identification of the patient

1. Name

_____ | | | _____

2. Age in years

3. Discharge date | | | | | | |

4. If the patient was not discharged the same day as the surgery, specify the reason.

……

……

……

……

……

……

……

……

Appendix 8. Follow up 2 weeks(for participant)

Patient study number

Filled in by _____

Date and place _____

Identification of the patient

1.Name_____

2. Name of district _____

3. Village name_____

4. Mobile phone number 1 _____

5. Mobile phone number 2 _____

6. Mobile phone number 3 _____

7. Local chairman_____

8. Phone number of local chairman _____

9. Occupation_____

10. Place of work (if any) _____

11. Additional contact information _____

_____

_____

_____

Patient study number

Follow up interview (for participant)

12. Have you had any complications or problems after the hernia surgery?

Wafunyeku obuzibu bwona bwona ng'omaze okulongosebwa?

1=yes, 2=no, 3=other

(specify).....

13. If yes, which kind of problem(s) did you have?..... | | | |

1= pain, more than expected which demanded more pain killers/additional or exchange of painkillers, 2=Bleeding; discoloration of the skin around the wound or the scrotum,
3=bleeding; significant swelling and tension of the skin, not only miscoloration, 4=Infection; which needed antibiotics, 5= Infection which demanded that the wound be opened, 6=significant problem to urinate; with need for catheterization, 7=Pain in a testicle; the same side as the operated hernia, 8=embolus (blood clot) in leg or lung, 9=pneumonia, 10=Cardiac infarction, 11= Recurrence of the hernia, 12=Other (specify)

14. If there was a problem or complication, how severe was it?

Obuzibu bwe wafunye, bubaire bwaghaha? .....

1=Tibwamani einho (mild), 2=intermediate/moderate,
3=Bwamani (severe), 4= Buyinza okusanya w'obulamu (life threatening)

15. Are you satisfied with the result of your surgery so far?

Olimusanufhu ne biviremu mu kulongesebwa?

1=yes, 2=no, 3=other_____

16. Have you sought and/or accessed health care for the hernia/wound after the surgery?

Patient study number

Wafunyeku obwindadhabi bwa hania oba obwe kiwundu obundi ngomaze

okulongosebwa

1=yes, 2=no

17. Would you recommend a friend or relative to be operated for hernia under local anaesthesia?

Osobola okusikiriza mukwanogwo oba owo luganda okulongosebwa hania nga basanalaziza hania yonka?

1=yes, 2=no, 3=other_____ | |

18. Do you think that we should continue to perform hernia surgery as day case surgery?

Olowoza nti okulongoosa hania kugye mu maiso nga abalwaire baidha kwolwo, memale bairayo eka? | |

1=yes, 2=no, 3=other_____

19. Other comments and information

Waliwo ekindi kyoyenda okukoba?

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Appendix 9. Follow up 1 year

Patient study number

Filled in by _____

Date and place _____

Identification of the patient

1. Name _____

2. Name of district _____

3. Village name_____

4. Mobile phone number 1 _____

5. Mobile phone number 2 _____

6. Mobile phone number 3 _____

7. Local chairman_____

8. Phone number of local chairman _____

9. Occupation_____

10. Place of work (if any) _____

11. Additional contact information _____

_____

Patient study number

The following questions regard the pain that you have now or have had in your groin during the past week.

12. Tebeleza obulumi obusingha amaani bwowulile mu maago week ebise

Estimate the <u>worst pain</u> you have felt in the <u>operated groin</u> during this past week.

1. No pain □
   Wazira bulumi.
2. Pain present, but can easily be ignored □
   Obulumi buliwo, aye tibufaaku.
3. Pain present, cannot be ignored, but does not interfere with everyday activities □
   Obulumi buliwo , mbuwulira aye tibundobera kukola

   mirimu ya bulidho.
4. Pain present, cannot be ignored, interferes with concentration on chores and daily activities. □
   Obulumi buliwo, tibundhikiriza kukola mirimu yange bulidho.
5. Pain present, cannot be ignored, and interferes with most activities. □
   Obulumi buliwho, bundobera okukola emirimu yange bulidho.
6. Pain present, cannot be ignored, and necessitates bed rest. □
   Obulumi buliwho, mba mukitanda buli kiseera.
7. Pain present, cannot be ignored, prompt medical advice sought. □
   Obulumi buliwho, nafunyeku obwindhandhabi.

If the patient answered no pain in question 12, please continue with question 13 and then questions 17 -20

13. If you answered “no pain” to question 10 above, try to remember when the pain in the operated groin disappeared after the operation.

1. The pain in the operated groin disappeared within 1 month after the operation. □
   Obulumi mu luuyi olwa longosebwa bwagya mu mwezi mulala.
2. The pain in the operated groin disappeared 1-3 months after the operation. □
   Obulumi mu luuyi olwa longoseebwa lwagya wagati womwezi mulala ne satu.

Patient study number

□

3. The pain in the operated groin disappeared 4-6 months after the operation.
   Obulumi mu luuyi olwalongoseebwa bwaja mu myezi inha n'omukaaga.

4. The pain in the operated groin disappeared 7-12 months after the operation. □
   Obulumi mu luyi olwalongoseebwa bwaja mu myezi musanvi n'omwaka

5. The pain in the operated groin disappeared recently. □
   Obulumi mu luyi olwalongoseebwa bwakaja butibuti.

If the patient has felt pain in the operated groin *during the past week*, please answer question 14 and 15.

14. How often have you felt pain in the operated groin during the past week?

Obulumi mu luuyi olwa longoseebwa obaire obuwulira otya?

1. Once a week. □
   Mulundi mulala mu sabiiti
2. 2-5 times a week. □
   Emirundi ng'ebiri ku etaano mu sabiiti
3. Every day. □
   Buli lunaku mbuwulira
4. Every day and also during night time. □
   Buli lunaku omusana ne kiro
5. I have had pain the whole week, both day and night □
   Obulumi mbuwulira sabiiti yona yona omusana ne kiro.

15. Have you taken pain-killers for pain in the operated groin during the past week?

Wamizeko amakerenda gobulumi ngomaze okulongosebwa sabiiti ebiseho?

1=no, 2=yes,
3=other.....

16. To what extent has pain in the groin limited your working capability/capacity to perform daily activities in the last 2 months?

Patient study number

Nenda okugerageranya obunene bw'obulumi bwo baire owulira nobusobozi bwo kukola emirimo yo buli lunaku.

1. I have been performing my normal activities as usual □
   Emirimo yange mbaire ngikola bulungi buli lunaku

2. The pain made me abstain from normal activity 1-7 days during the last 2 months □
   Obulimi bwandobera okukola emirimu yange wagati yolunaku lulala n'omusanvu mu myezi ebiri ebiseeho.

3. The pain made me abstain from normal activity 1-4 weeks during the last 2 months □
   Obulumi bwandobera okukola wagati ya sabiiti ndala ku inha mu myezi ebiri ebiseho.

4. The pain has made me abstain from normal activity for the whole of the last 2 months □
   Obulumi bwandobeire okukola okumala emyezi ebiri yona yona ebiseho.

17. How is it today with pain and other complaints in the operated groin compared?

to the pain and complaints before the operation? Is it the same, more or less?

Obulumi bulibutya buti ngo geraganya nebibaire bikuluma ku luyi olwa longoseebwa. Obulumi nobwo, bukendeire obwa bweyongeire. □

1=Less, 2=The same, 3=More

18. Are you fully recovered in the operated groin? □

Owonye bulungi ku luuyi olwa longoseebwa

1=yes, 2=no, 3=other

19. If no, which remaining problems do you have? □

Bwoba okaali kuwona ekindi ki?

Patient study number

1=Pain, 2=limited physical movement, 3=numbness,

20. Are you satisfied with the results of your hernia surgery?

Oli musanafu nebivireemu mu kulongosebwa?

a.Yes, b. No

21. Have you been operated on for hernia or had an abdominal operation since the hernia operation at _____ ____Hospital in 20____?

Walongoseebwako hania or okulongosebwa ku nda ngomaze

okulongesebwa hania?

1=yes, 2=no, 3=other.....

Patient study number

Date (dd /mm/ yy)

Physical examination(for participant)

22. Clinical examination

1. Operation wound healed properly, 1=yes, 2=no
2. Remaining discomfort, 1=yes, 2=no
   If yes, in what way? ……
3. Recurrent hernia, 1=yes, 2=no
4. Other……
   ……

23. Complications after the surgery?

1=None, 2=miscoloration of the skin,
3=hematoma, 4=superficial infection, 5=deep infection, 6=severe palpatory pain in the groin, 7=other……

24. If there is a problem or complication, how severe is it?

1=Mild, 2=intermediate/moderate, 3=severe, 4= life threatening

Complication	**Definition**
Hematoma	Bleeding causing significant tissue distension, bruising excluded
Urinary retention	Need for catheterisation
Infection	Local signs of inflammation, purulent secretion and/or positive wound culture
Severe pain	Out of the expected postoperative pain
Other complication	seroma, thromboembolism, cardiovascular, infections other than in the wound
Need for reoperation, other than recurrence	
Death	

Patient study number

25. Other comments and information

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Examination by (name + signature) _____

Appendix 10. Follow up after 3 years

Patient study number

Filled in by _____

Date and place _____

Identification of the patient

1. Name _____

2. Name of district _____

3. Village name_____

4. Mobile phone number 1 _____

5. Mobile phone number 2 _____

6. Mobile phone number 3 _____

7. Local chairman_____

8. Phone number of local chairman _____

9. Occupation_____

10. Place of work (if any) _____

11. Additional contact information _____

_____

Patient study number

The following questions regard the pain that you have now or have had in your groin during the past week.

12. Tebeleza obulumi obusingha amaani bwowulile mu maago week ebise

Estimate the <u>worst pain</u> you have felt in the <u>operated groin</u> during this past week.

8. No pain □
   Wazira bulumi.
9. Pain present, but can easily be ignored □
   Obulumi buliwo, aye tibufaaku.
10. Pain present, cannot be ignored, but does not interfere with everyday activities □
    Obulumi buliwo , mbuwulira aye tibundobera kukola mirimu ya bulidho.
11. Pain present, cannot be ignored, interferes with concentration on chores and daily activities. □
    Obulumi buliwo, tibundhikiriza kukola mirimu yange bulidho.
12. Pain present, cannot be ignored, and interferes with most activities. □
    Obulumi buliwho, bundobera okukola emirimu yange bulidho.
13. Pain present, cannot be ignored, and necessitates bed rest. □
    Obulumi buliwho, mba mukitanda buli kiseera.
14. Pain present, cannot be ignored, prompt medical advice sought. □
    Obulumi buliwho, nafunyeku obwindhandhabi.

If the patient answered no pain in question 12, please continue with question 13 and then questions 17 -20

13. If you answered "no pain" to question 10 above, try to remember when the pain in the operated groin disappeared after the operation.

6. The pain in the operated groin disappeared within 1 month after the operation. □
   Obulumi mu luuyi olwa longosebwa bwagya mu mwezi mulala.
7. The pain in the operated groin disappeared 1-3 months after the operation. □
   Obulumi mu luuyi olwa longoseebwa lwagya wagati womwezi mulala ne satu.

Patient study number

□

8. The pain in the operated groin disappeared 4-6 months after the operation.
   Obulumi mu luuyi olwalongoseebwa bwaja mu myezi inha n'omukaaga.

9. The pain in the operated groin disappeared 7-12 months after the operation. □
   Obulumi mu luyi olwalongoseebwa bwaja mu myezi musanvi n'omwaka

10. The pain in the operated groin disappeared recently. □
    Obulumi mu luyi olwalongoseebwa bwakaja butibuti.

If the patient has felt pain in the operated groin *during the past week*, please answer question 14 and 15.

14. How often have you felt pain in the operated groin during the past week?

Obulumi mu luuyi olwa longoseebwa obaire obuwulira otya?

6. Once a week. □
   Mulundi mulala mu sabiiti
7. 2-5 times a week. □
   Emirundi ng'ebiri ku etaano mu sabiiti
8. Every day. □
   Buli lunaku mbuwulira
9. Every day and also during night time. □
   Buli lunaku omusana ne kiro
10. I have had pain the whole week, both day and night □
    Obulumi mbuwulira sabiiti yona yona omusana ne kiro.

15. Have you taken pain-killers for pain in the operated groin during the past week?

Wamizeku amakerenda gobulumi ngomaze okulongosebwa sabiiti ebiseho?

1=no, 2=yes,
3=other.....

16. To what extent has pain in the groin limited your working capability/capacity to perform daily activities in the last 2 months?

Nenda okugerageranya obunene bw'obulumi bwo baire owulira nobusobozi bwo kukola emirimo yo buli lunaku.

1.I have been performing my normal activities as usual □
Emirimo yange mbaire ngikola bulungi buli lunaku

2.The pain made me abstain from normal activity 1-7 days during the last 2 months □
Obulimi bwandobera okukola emirimu yange wagati yolunaku lulala n'omusanvu mu myezi ebiri ebiseeho.

3.The pain made me abstain from normal activity 1-4 weeks during the last 2 months □
Obulumi bwandobera okukola wagati ya sabiiti ndala ku inha mu myezi ebiri ebiseho.

4.The pain has made me abstain from normal activity for the whole of the last 2 months □
Obulumi bwandobeire okukola okumala emyezi ebiri yona yona ebiseho.

17. How is it today with pain and other complaints in the operated groin compared?

to the pain and complaints before the operation? Is it the same, more or less?

Obulumi bulibutya buti ngo geraganya nebibaire bikuluma ku luyi olwa longoseebwa. Obulumi nobwo, bukendeire obwa bweyongeire. ☐

1=Less, 2=The same, 3=More

18. Are you fully recovered in the operated groin?

Owonye bulungi ku luuyi olwa longoseebwa ☐

1=yes, 2=no, 3=other

19. If no, which remaining problems do you have? ☐

Bwoba okaali kuwona ekindi ki?

1=Pain, 2=limited physical movement, 3=numbness,

20. Are you satisfied with the results of your hernia surgery?

Oli musanafu nebivireemu mu kulongosebwa? ☐

a.Yes, b. No

Patient study number

21. Have you been operated on for hernia or had an abdominal operation since the hernia operation at _____ ____Hospital in 20____?

Walongoseebwako hania or okulongosebwa ku nda ngomaze

okulongesebwa hania?

1=yes, 2=no, 3=other.....

Patient study number

Date (dd /mm/ yy)

Physical examination

22. Clinical examination

5. Operation wound healed properly, 1=yes, 2=no
6. Remaining discomfort, 1=yes, 2=no
   If yes, in what way? ……
7. Recurrent hernia, 1=yes, 2=no
8. Other……
   ……
   ……..

23. Complications after the surgery?

1=None, 2=miscoloration of the skin,
3=hematoma, 4=superficial infection, 5=deep infection, 6=severe palpatory pain in the groin, 7=other……

24. If there is a problem or complication, how severe is it?

1=Mild, 2=intermediate/moderate, 3=severe, 4= life threatening

Complication	**Definition**
Hematoma	Bleeding causing significant tissue distension, bruising excluded
Urinary retention	Need for catheterisation
Infection	Local signs of inflammation, purulent secretion and/or positive wound culture
Severe pain	Out of the expected postoperative pain
Other complication	seroma, thromboembolism, cardiovascular, infections other than in the wound
Need for reoperation, other than recurrence	
Death	

Patient study number

25. Other comments and information

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Examination by (name + signature) _____

Patient study number

Appendix 11. Post operative information for patients

Expected symptoms and recommendations after the surgery.

Obubonero obusuubilwa n'ebinakolebwa nga okulongoosebwa kuweire.

- After the surgery you will feel some pain. Diclofenac, Ibuprofen and paracetamol will be sufficient in reducing this pain most of the time. You should not use Aspirine or Diclofenac before surgery since they increase the risk for bleeding.

  Ng'omaze okulongoosebwa, oidha kuwulira muku obulumi butono. Panado aida kuba nga amala okukendeezaku obulumi bunno ebiseera ebisinga. Totekeirwa kukozesa asupilini oba dikulofenaka okuva lwebili nti byongera ku buzibu obw'okuduludha omusaayi.

- Because of the pain, you may not be able to perform all normal activities during the first 10-14 days after the surgery. However, it is important to be physically active and move around as usual.

  Kulw'obulumi,oyinza obutasobola kukola mirimo gyo egyabulidho mu sasira/wiki 10-14 edhisooka nga wakalongoosebwa. Wabula, kyamugaso inho okuba ng'okozesa omubili gwo era otambule tambuleku agho nga buliidho.

- Small bleedings in the skin are common. They may discolor the wound area and may also give a discoloration of the scrotum. This is harmless and it will disappear within 30 days.

  Okusabuka sabuka okutono mu luwusu bitera okubaagho. Biyinza okukyuusa langi agho waibwa era biyinza n'okukyuusa langi y'akasagho ak'enkulo (amaye). Kino kizira bulabe era kiidha kughawo munaku 30.

- The scar will be somewhat thick and hard during the first months after the surgery. With time, the scar softens.

  Enkovu eidha kuba nnene muku era nga ngumu mumyezi egisooka nga wakalongoosebwa. Nga wabise akaseera, enkovu egonda

- Numbness around the scar is common but harmless.

  Okusanhalala w'enkovu kitera okubaagho aye kizira bulabe.

- The sutures will be removed at the post operative control after 14 days. At the same visit, you will be seen by a medical doctor for physical examination in order to find complications at an early stage.

  Ewuuzi diidha kutoolebwagho……Ku lukyala olulala olwo,oidha kubonebwa omusawo ow'ebyobulamu aidha okukebera abonhe nti azura obuzibu nga bwakatandika.

Patient study number

Possible complications that need medical attention. Obuzibu obutono tono obwetagisa okubonebwa oweby'obulamu.

- Infection in the wound. The wound becomes very swollen and painful and sometimes pus drains from the wound. *Obulwaire mu kiwundu. Ekiwundu kizimba inho era kyaruma n'ebiseera ebindhi amasira gakulukuta okuva mu kiwundu.*
- Hematoma. Significant bleeding under the skin so that the wound and/or scrotum becomes swollen
- If you experience these or any other problems after the surgery, we encourage you to contact Dr Alphonsus Matovu, phone number 0774 287 185 to discuss the problems and plan an extra check up if necessary.

The planned control after 14 days will take place the ……(date)

at ……..(time) at …… (Location)

by Dr. …….

Appendix 12:WHO Surgical safety check list.

Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia
(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision
(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room
(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

Appendix 13: Adverse event classification and reporting tool.

(Adapted from PEPFAR's best practices for Voluntary Medical Male Circumcision site operations; Chapter 7.Managing, Monitoring, Reporting VMMC Adverse events).

Encircle as appropriate

Participant number

Adverse event	Mild	Moderate	Severe
AN. Anaesthetic related problem			
Surgery	Mild localized allergic reaction at injection site without swelling and allergic reaction	Symptoms of reaction to anesthetic including light headedness, nervousness or dizziness. These symptoms may resolve on their own and may not necessitate use of emergency commodities such as medicines or equipment from the emergency kit. These symptoms do not require admission to hospital or transfer to another health facility.	Symptoms of severe systemic allergic reaction to local anesthetic including rash, urticaria, angiooedema and shortness of breath, or symptoms of overdose of local anaesthetic including light headedness, nervousness, confusion, dizziness, drowsiness, ringing of ears, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, braddycardia or hypotension requiring use of medicines or equipment from the emergency kit, or emergency commodities or hospitalization to manage.

BL. Bleeding			
Surgery	Intra operative bleeding that is more significant than usual or post operative spotting of the bandage with blood, both easily controlled.	Intraoperative bleeding or bleeding that occurs prior to discharge that requires a pressure dressing to control or that requires additional skin sutures without surgical re-exploration of the wound.	Intraoperative bleeding requiring blood transfusion, transfer to another facility, or hospitalization or transfer to another facility.
PA. Pain			
Surgery	Client expresses discomfort, however is able to remain still and co-operate for the procedure. No additional local anaesthetic is required.	Pain requiring additional local anesthesia	Pain not responsive to additional local anesthesia.
POST OPERATIVE PERIOD			
BL. Bleeding			
Surgery	Blood stained dressing or underwear, no active bleeding. Small amount of bleeding from minor clot disruption when changing dressings that is controllable with new dressing or within 5-10mins of manual pressure measured on a clock.	Bleeding that is not controlled by a new dressing or within 5-10mins of manual pressure measured on a clock, or requires return to the health facility for a pressure dressing or additional skin sutures without surgical re-exploration of the wound	Bleeding that requires surgical re-exploration, hospitalization or transfer to another facility or any case where blood transfusion or iv, fluids is necessary.

IN. Infection			
Surgery	Erythema or traces of serous discharge or infective process noted at wound margin. No intervention required other than observing wound hygiene.	Discharge from the wound, painful swelling with erythema, or elevated temperature requiring the use of oral antibiotics.	Cellulitis or abscess of the wound or infection severe enough to require surgical intervention, hospitalization, intravenous or intramuscular antibiotics.
PA. Pain			
Surgery	Participant complains of pain , not requiring more than standard post operative analgesia and considered within normal thresholds	Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activity. On a Visual analogue scale it is scored 5-7 on a scale of 1-10.	Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activity. On a Visual Analogue Scale it is scored 8-10 on a scale of 1-10.

Appendix 14: Costing of groin hernia repair methods

Participant number

SN	**Types of medicines used**	**Amount in mls or gms**	**Cost on UGX**	**Cost in USD**
a	Flucloxacillin	1.5gms		
b	Clindamycin	900gms		
c	Lidocaine			
d	Ropivacaine			
e	Paracetamol			
f	Ibuprofen			
g	Mesh			
h	Sutures i. ii. iii. iv. v. vi			
	Cost of the operation	**Quantity**	**Cost in UGX**	**Cost in USD**
a	Cost of procedure			
b	Cleaning of operating rooms			
c	Cleaning of equipment			
c	Sterilisation of equipment			
e	Cleaning of linen			

f	Sterilization of the linen			
	Human resource costs			
a	Surgeon			
b	Medical officer			
c	Scrub nurse			
d	Instrument nurse			
e	Ward nurse			
Top up administrative costs				
g	Electricity			
h	Water			
	Additional information			

Appendix 15: Work plan for the study.

Work plan for female groin hernia surgery study.			
Serial number	**Activity**	**Date**	**Persons responsible**
1	Completing study documents	September-2018	Matovu
2	Submission of study documents	October –November 2018	Matovu
3	Submission to UNCST	November -2018	Matovu
5	Processing Practicing Licenses for visting investigators	November -2018	Matovu
6	Mobilisation of participants	January 2019	Matovu
7	Training surgeons	February-2019	Pär, Andreas, Alphons, Jenny
8	Continuing surgeries for participants	February to May 2019	Matovu
9	2 week follow up of participants	February to June 2019	Matovu
10	Data entry and filtering	July-2019	Matovu
10	One year follow up of participants	February to June 2020	Matovu
11	Completion of data entry	March-2020	Matovu
12	Three year follow up	February to May 2022	Matovu
12	Writing manuscript	Ongoing	Matovu, Jenny, Pär, Andreas