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Open mesh groin hernia repair in women - a comparison of two surgical methods

Submission date 31/12/2018	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/06/2019	**Overall study status** Stopped	
Last Edited 17/07/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
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. 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. 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.

Groin hernia repair is the commonest general surgical procedure performed globally. 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. In the emergency setting, mortality is higher for women than for men undergoing hernia repair. This inequity warrants further investigation and correction.

Laparoscopic approach is considered the gold standard in mesh hernia repair in women (14). 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.

The aims of this study are:
1. Evaluate and compare the outcomes after hernia repair using the anterior mesh repair and the modified version of the anterior mesh repair in adult females.
2. Calculate (and compare) costs and cost-effectiveness of this procedure (of the modified anterior mesh repair against the Lichtenstein method.

Who can participate?
Adult women without significant comorbidities (ASA class 1 and 2) with primary, reducible groin hernia.

What does the study involve?
Study participants will be randomised to being operated using an anterior mesh repair or a modified anterior mesh repair for their groin hernia. The surgery will be done under local anaesthesia as day case surgery. Prior to inclusion into the study, patients will be physically examined including ultrasonography of the groins.

What are the possible benefits and risks of participating?
Surgery is always associated with certain risks. The risk of elective groin hernia repair is however small. The patients will be operated on by consultant surgeons which is rare in Uganda. The patients will also be followed up after 2 weeks, 1 and 3 years. No costs are associated with the surgeries for the study participants.

Where is the study run from?
The study will be carried out in several hospitals in Uganda. There are 11 tentative hospitals but the number who will actually contribute to the study will depend on how well recruitment and inclusion of patients into the study goes.

When is the study starting and how long is it expected to run for?
Inclusion of patients into the study will begin in October 2019. We expect the recruitment to be completed during 2020. Follow-up will be done between 2020 and 2023.

Who is funding the study?
The study is funded through grants from the Swedish Medical Society and the Swedish Research Council.

Who is the main contact?
Jenny Löfgren, jenny.lofgren@ki.se
Alphonsus Matovu, alphonsusing@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Jenny Löfgren

ORCID ID
https://orcid.org/0000-0001-5884-0369

Contact details
Department of Molecular Medicine and Surgery
Karolinska Institutet
Karolinska University Hospital, Solna (L1:00)
Stockholm
Sweden
17176

+46 704 612426
jenny.lofgren@ki.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

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

Acronym
FemRep

Study objectives
There will be no clinically or statistically significant differences in terms of the primary and secondary endpoints when comparing the two surgical methods under study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mildmay Uganda - Research Ethics Committee, 20/12/2018, ref. 0110-2018.

Study design
Interventional multi-centre double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Groin hernia

Interventions
Current interventions as of 20/07/2020:
All patients will be physically examined for the presence of a groin hernia. All patients will be operated for their groin hernia. Two techniques will be used. The duration of the surgery will be 1-2 hours in most cases, depending on the level of complexity. All patients will be followed up after 2 weeks, 1 year and 3 years. Patients will be randomised to the control or experimental group after diagnosis has been assured. A computer-based program will be used and the randomisation will be done by a nurse. If a patient randomised to the control arm is found to have a femoral hernia (intraoperatively) she will cross over to the experimental arm).

Control arm: Anterior mesh repair according to Lichtenstein, under local anaesthesia. Due to a large proportion of femoral hernias among the study participants, the transversals fascia will be opened to make examination for femoral hernia possible also for patients in the control arm. This change was implemented after the first 84 patients had been included in the study.

Experimental arm: Modified anterior mesh repair under local anaesthesia. All steps are the same as for the control arm but in addition, the transversals fascia is opened and a slit of the mesh is fixed to cover the femoral canal.

Previous interventions:
All patients will be physically examined, including ultrasonography of the groin, for diagnosis. All patients will be operated for their groin hernia. Two techniques will be used. The duration of the surgery will be 1-2 hours in most cases, depending on the level of complexity. All patients will be followed up after 2 weeks, 1 year and 3 years. Patients will be randomised to the control or experimental group after diagnosis has been assured. A computer-based program will be used and the randomisation will be done by a nurse. If a patient randomised to the control arm is found to have a femoral hernia (intraoperatively) she will cross over to the experimental arm).

Control arm: Anterior mesh repair according to Lichtenstein, under local anaesthesia.

Experimental arm: Modified anterior mesh repair under local anaesthesia. All steps are the same as for the control arm but in addition, the transversals fascia is opened and a slit of the mesh is fixed to cover the femoral canal.

Intervention Type
Procedure/Surgery

Primary outcome measure
Recurrence will be determined by a blinded observer through physical examination at 1 and 3 years. In unclear cases, ultrasonography will be used in addition to the physical examination.

Secondary outcome measures
1. Postoperative complications will be determined through physical examination by a blinded observer at 2 weeks.

2. Self-Assessed health status will be measured using a health thermometer where 0 represents the worst imaginable health, and 100 represents the best imaginable health. This is done preoperatively, at 2 weeks, 1 year and 3 years.
3. Patient satisfaction will be measured through asking the study participants "are you satisfied with the result of the operation?" as well as "are your level of groin symptoms less, the same or worse compared to before the surgery?". This is done at 1 and 3 years.
4. Cost and cost-effectiveness of the interventions will be calculated in terms of cost in USD per DALY averted. The IPQ results will be translated into disability weights for DALY calculation. Costs will be assessed from the providers perspective, including information on materials and medicines, staff costs, capital costs and overhead costs.
5. Chronic pain will be measured using the Inguinal Pain Questionnaire. Level of pain will be assessed before the operation, and at 1 and 3 years postoperatively

Overall study start date
01/01/2017

Completion date
01/02/2024

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Female
2. Primary, reducible groin hernia
3. ASA class 1-2

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
440 + 50

Total final enrolment
200

Key exclusion criteria
1. Recurrent hernia
2. Alcohol or substance abuse
3. Known or suspected coagulopathy

Date of first enrolment

07/10/2019

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
Uganda

Study participating centre
Arua Regional Referral Hospital
Arua
Arua
Uganda
N/A

Study participating centre
Mubende Regional Referral Hospital
Mubende
Mubende
Uganda
N/A

Study participating centre
Hoima Regional Referral Hospital
Hoima
Hoima
Uganda
N/A

Study participating centre
Jinja Regional Referral Hospital
Jinja
Jinja
Uganda
N/A

Study participating centre
Iganga General Hospital
Iganga

Iganga
Uganda
N/A

Study participating centre
Buluba Mission Hospital
Buluba
Jinja
Uganda
N/A

Study participating centre
Kitovu Mission Hospital
Masaka
Masaka
Uganda
N/A

Study participating centre
Tororo General Hospital
Tororo
Tororo
Uganda
N/A

Study participating centre
Kitgum General Hospital
Kitgum
Kitgum
Uganda
N/A

Study participating centre
Lacor Mission Hospital
Gulu
Gulu
Uganda
N/A

Study participating centre
Kamuli Mission Hospital
Kamuli
Kamuli
Uganda
N/A

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Department of Molecular Medicine and Surgery
Karolinska University Hospital, Solna (L1:00)
Stockholm
Sweden
17176

Sponsor type
University/education

Website
https://www.ki.se

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Government

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Svenska Läkaresällskapet

Alternative Name(s)
Swedish Society of Medicine, Swedish Medical Society, SLS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

Results and Publications

Publication and dissemination plan
Study findings will be published after the one year and the three year follow up. Cost and cost effectiveness analysis will be published separately from the clinical findings.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Jenny Löfgren (jenny.lofgren@ki.se). The data available will be raw data (original or scanned forms or in excel format) and it will be available from the time of publication based on the one year follow up. Raw data will be stored for 10 years. We do not expect to share data for research purposes but it will be made available by request from reviewers or the journals where we submit the manuscripts. Sharing of data is not part of the patient consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/07/2025	17/07/2025	Yes	No