

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

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Registration date 10/06/2019	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/07/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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

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