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Simulation-based training for inguinal hernia repair: a randomized trial

Submission date
22/08/2023

Recruitment status
Recruiting

Registration date
18/01/2024

Overall study status
Ongoing

Last Edited
30/12/2025

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Task sharing with medical doctors without formal surgical training is widely practiced in the public healthcare sector In Uganda. Intern doctors are expected to learn how to perform this procedure during their internship. A standardized training program for inguinal hernia repair for intern doctors could improve the quality of service as well as volume in the long run.
The aim of this study is to investigate whether simulation-based learning on a 3D-printed plastic scaffold prior to performing supervised surgeries affects the learning curve of trainees compared to performing supervised surgeries alone.

Who can participate?
Trainees (non-surgeon medical doctors) and male patients with primary, reducible inguinal hernias

What does the study involve?
For the trainees, the study involves simulation-based training on a 3D model under supervision (intervention group) and supervised operations on patients (both intervention and control groups).
For the patients, the study involves undergoing an open anterior mesh repair under local anaesthesia by a supervised trainee.
The study involves collecting data at inclusion in the study and at 2 weeks, 1 year and 3-5 years after the surgery.

What are the possible benefits and risks of participating?
For the trainees, the benefit is that they learn how to perform an open anterior mesh repair under local anaesthesia through a standardised program with supervision. There are no direct risks to the trainees through participating in this study.
For the patients, the main benefit is that they will receive a state-of-the art surgical procedure which is not always available to patients in Uganda due to the costs of the material used. They will be operated on by non-surgeons under the supervision of specialist surgeons, which is not always the case in the study settings.

Where is the study run from?
Mubende and Soroti Regional Referral Hospitals (Uganda)

When is the study starting and how long is it expected to run for?
January 2019 to December 2030

Who is funding the study?
The Swedish Research Council (Sweden)

Who is the main contact?
Dr Jenny Löfgren, jenny.lofgren@ki.se

Contact information

Type(s)
Principal investigator

Contact name
Dr Jenny Löfgren

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Simulation-based training for mesh inguinal hernia repair under local anaesthesia: a randomized trial

Study objectives
Simulation-based training will reduce the number of supervised surgeries needed to reach proficiency by at least 20%.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/01/2024, MildMay Institutional Review Board (12 Km Entebbe Road, Naziba Hill, Lweza, Kampala, PO Box 24985, Uganda; +256 (0)312 210 200; mailbox@mildmay.or.ug), ref: 1

Primary study design
Interventional

Study design
Parallel-group randomized controlled trial with superiority design

Study type(s)
Treatment, Other

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

Interventions
A computer-based program will be used for the randomisation. Blocks of 4, 6 and 8 will be when generating the sequence. Randomisation will be done at inclusion in the study for the trainees and immediately prior to the surgical procedure for the patients.

1. Simulation-based training on 3D inguinal hernia model for non-surgeon medical doctors
2. Inguinal hernia repair on patients

For the trainees, the study involves simulation-based training on a 3D model under supervision (intervention group) and supervised operations on patients (both intervention and control groups).
For the patients, the study involves undergoing an open anterior mesh repair under local anaesthesia by a supervised trainee.
The study involves collecting data at inclusion in the study and at 2 weeks, 1 year and 3-5 years after the surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Number of procedures needed to reach competence to independently perform inguinal hernia repair. Measured during the training intervention and filled out in a questionnaire.

Key secondary outcome(s)
1. Postoperative complications measured through interview and physical examination 2-4 weeks postoperatively
2. Hernia recurrence measured through physical examination 1 year and 3-5 years postoperatively
3. Chronic pain, quality of life and patient satisfaction measured through questionnaire-based interviews and physical examination at 1 year and 3-5 years postoperatively
4. Trainee rating of the training experience measured at the finalisation of training intervention using questionnaires
5. Trainee ability to name anatomical structures on the model and in a patient, measured during the training intervention using questionnaires filled out by the trainer

6. Number of procedures needed to perform a hernia repair on the model to reach proficiency on the model measured during training and filled out by the trainer in a questionnaire
7. Number of procedures performed during 12 months after the training intervention, self-reported by trainees in a questionnaire, 1 year after the training intervention
8. Trainee skill retention 1 year after the training intervention, assessed by the trainer using a questionnaire, 1 year after the training intervention
9. Rating of the training experience by the trainers, measured through a questionnaire at the end of the training intervention
10. Cost of the training intervention and cost per surgery measured by including direct and indirect costs from the trainer and health care provider's perspective. Measured at the time of the implementation of the surgical training program.
11. Cost-effectiveness of the training intervention expressed in cost per trainee to reach proficiency, cost-effectiveness of surgical procedure expressed as cost per disability-adjusted life year (DALY) averted. Costs measured as 10 (above). Training effectiveness = same as the primary outcome. DALYs calculated based on information from 3 above, measured using a questionnaire (EQ5D-3L) preoperatively compared to 2 weeks, 1 year and 3-5 years postoperatively.

Completion date
31/12/2030

Eligibility

Key inclusion criteria
Trainees:
1. Employed as intern doctor/recently completed internship in a Ugandan hospital
2. Interest in surgery
3. Willingness to participate in the study

Patients:
1. Adult men 18 years and above, (this is the age of consent and below 15 years of age the body is still growing making it inappropriate to use mesh repair)
2. Primary, reducible groin hernia
3. ASA class 1 and 2 (47)
4. Willingness to participate in the study and ability to give a written informed consent

Participant type(s)
Learner/student, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Trainees:
1. Does not meet the inclusion criteria

Patients:
1. Recurrent hernia
2. Incarcerated groin hernia requiring emergency operation
3. Known coagulopathy (including medically induced, but not including daily usage of low-dose aspirin)
4. 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 criterion. Lab tests will not be used to diagnose drug or alcohol abuse.

Date of first enrolment
01/05/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Uganda

Study participating centre
Mubende Regional Referral Hospital
Plot M.4 Kakumiro Road
Mubende
Uganda
PO Box 4

Study participating centre
Soroti Regional Referral Hospital
Mohamadan Road
Soroti
Uganda
PO Box 289

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

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

Results and Publications

Individual participant data (IPD) sharing plan
The metadata of the present study will be openly accessible through Karolinska Institutet. Raw data including patient identifiers will not be publicly accessible. Raw data may be shared upon request guaranteed that the recipient has the required ethical approvals.

The name and email address of the investigator/body who should be contacted for access to the datasets: Jenny Löfgren, jenny.lofgren@ki.se.
Dates of availability: After completion of the study
Whether consent from participants was required and obtained: Participants will give written informed consent
Any ethical or legal restrictions: Data sharing other than metadata will require ethical approval

IPD sharing plan summary

Available on request