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3D simulation for groin hernia repair for novice surgical learners - a randomized trial

Submission date	Recruitment status	[_] Prospectively registered
26/08/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/11/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/11/2023	Surgery	[_] Record updated in last year

Plain English summary of protocol
Background and study aims?
Hernia is a commonly performed surgical procedure and often one of the first for residents in general surgery to learn. Simulation based learning prior to performing surgery on patients can be a way to accelerate learning and reducing risks to patients. In this study, the learning process through simulation based training on a 3D groin hernia model is investigated. Medical students will participate in the study as they represent novice surgical learners.

The main aim of this study is to evaluate the feasibility of model based simulation for open groin hernia repair for novice learners in surgery.

Who can participate?
The students will primarily be recruited from course participants in the elective course on global surgery, for medical students at Karolinska Insitutet. If needed, additional students and intern doctors will be recruited.

What does the study involve?
The study involves participating in a one-week training course in groin hernia. All study participants will have access to study materials including written and video materials and 3D models. The study participants will be randomly allocated to the control group (self-directed learning) or the intervention group (supervised training).

The study participants will have the opportunity to practice on the models during one whole week, in a simulation lab at Karolinska Institutet.

When they think that they are ready, the study participants will be examined one-on-one. The examination will be video recorded and an external surgeon who did not participate in the training will score the study participants proficiency according to the OPRS score for mesh groin hernia repair.

One month after the training intervention, the retention of the anatomical knowledge and ability to perform a mesh repair on a model will be assessed.

What are the possible benefits and risks of participating?
The possible benefit for the study participants is that they will learn more about groin hernia repair and will be able to practice this common procedure on 3D models in a safe environment. The main risk is related to handling of sharp objects (scalpel and sutures).

Where is the study run from?
Karolinska Institutet in Stockholm (Sweden)

When is the study starting and how long is it expected to run for?
March 2019 to December 2026

Who is funding the study?
The Swedish Research Council

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

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Simulation based training for hernia mesh repair for novice learners in Sweden – a randomized trial

Study objectives
Supervised training on the 3D model compared to self-guided training will lead to a higher level of proficiency to carry out a mesh hernia repair on the model at the point of examination.

Ethics approval required
Ethics approval not required

Ethics approval(s)
We applied for ethical approval from the Swedish Ethical Review Authority and they concluded that ethical approval is not needed for this study.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Training facility/simulation

Study type(s)
Treatment

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Groin hernia repair student training

Interventions
At the start of the study, all study participants will receive oral and written information about the study. The trainers will go through the anatomy of the abdominal wall and the inguinal canal including important structures. Thereafter, video material about anterior mesh repair will be shown to the study participants. This includes an animated film of the steps of the repair, a video on how to set up the model and a video on how to perform an anterior mesh repair on the model. The links to these materials are sent to the participants on e-mail and they are free to access this material at any time.

After this the study participants will be randomised to either the intervention arm or to the control arm. The control arm will practice on their own with the models and the instruction material. The intervention arm will practice with the models and the instruction material and in

addition they will be supervised by instructors. The training lasts for one week. There will be a follow up at one month.

Intervention Type
Procedure/Surgery

Primary outcome measure
Score (1-5) on the American College of Surgeons Operative Performance Rating System (OPRS) for mesh groin hernia repair. Assessed as part of the examination immediately after the one-week training course.

Secondary outcome measures
1. Proportion of participants with a score of 4 or 5 on the OPRS. Assessed as part of the examination immediately after the one-week training course.
2. Ability to name anatomical structures relevant for groin hernia surgery. Assessed as part of the examination immediately after the one-week training course.
3. Retention of anatomical knowledge and surgical skills one month after the training course. Assessed through re-examination using the OPRS for groin hernia repair.
4. Students rating of the hernia training modules, questionnaire filled at the end of the one-week training course.

Overall study start date
01/03/2019

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Medical student or intern doctor with an interest for groin hernia surgery
2. Willingness to participate in the study

Participant type(s)
Learner/student

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
34

Key exclusion criteria

1. Having been the lead surgeon on one or more groin hernia repairs.
2. Having been the primary assistant on three or more groin hernia repairs.

Date of first enrolment
01/10/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Stockholm
Sweden
17177

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Department of Molecular Medicine and Surgery
Karolinska University Hospital, L1:00
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Sponsor type
University/education

Website
https://ki.se

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

Publication and dissemination plan
The results will be published in at least one manuscript in a peer-reviewed journal. Findings will be presented at conferences and meetings.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
Metadata will be available through the ELN system at Karolinska Institutet. Raw data may be available through the Primary Investigator granted reasonable justification and that required ethical approvals exist.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Swedish		01/11/2023	No	Yes
Protocol file	version 5	01/11/2023	01/11/2023	No	No