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Simulation-based training for groin hernia repair in Sierra Leone

Submission date 22/08/2023	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 01/09/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 09/01/2025	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The surgical human resource is a limiting factor in meeting the demands for surgical services in low-income settings. Groin hernia represents a common surgical condition and its repair is among the most commonly performed surgical procedures worldwide. Still, the number of procedures performed needs to increase drastically in order to meet the need for this procedure. In this study, trainees enrolled in the CapaCare surgical training program in Sierra Leone will participate in a simulation-based course in inguinal hernia repair.
The aim of the study is to investigate if the learning curve to learn how to perform inguinal hernia repair on patients is affected as a result of first learning how to perform this procedure on 3D models.

Who can participate?
Trainees enrolled in the CapaCare surgical training program in Sierra Leone.

What does the study involve?
The trainees will participate in the course which includes theory and practice. They will learn how to perform a sutured inguinal hernia repair on the 3D models and will be assessed for proficiency by the researchers. After completion of the course, they will report in an electronic format about the patients that they operated on as part of their training program. This reporting is routinely done by the trainees in the CapaCare surgical training program.

What are the possible benefits and risks of participating?
The participants will benefit as they learn how to perform this procedure, step-by-step, on a 3D model under supervision prior to operating on patients. There are no direct risks associated with participating in this study.

Where is the study run from?
Masanga Hospital (Sierra Leone)

When is the study starting date and how long is it expected to run for?
March 2019 to December 2027

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

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

Contact details
Department of Molecular Medicine and Surgery
Karolinska Institutet
Karolinska University Hospital, L1:00
Stockholm
Sweden
17176
+46 (0)704 612426
jenny.lofgren@ki.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Model-based training for groin hernia repair in Sierra Leone

Study objectives
Does model-based training for inguinal hernia repair influence the time to stabilisation of operation time?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/03/2020, Sierra Leone Ethics and Scientific Review Committee (Ministry of Health and Sanitation, Directorate of Training and Research, 5th floor, Youyi Building Brookfields, Freetown, 00000, Sierra Leone; +232 (0)78 366493; efoday@health.gov.sl), ref: SLESRC (Bolkan)

Study design
Prospective cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Training facility/simulation

Study type(s)
Other, 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
Inguinal hernia

Interventions
In this study, trainees will participate in a simulation-based training program for inguinal hernia repair which includes theory and practice. They will learn how to perform a sutured inguinal hernia repair on the 3D models and will be assessed for proficiency by the researchers. After completion of the course, they will report in an electronic format about the patients that they operated on as part of their training program. This reporting is routinely done by the trainees in the CapaCare surgical training program.

Intervention Type
Procedure/Surgery

Primary outcome measure
Stabilisation of operation time measured through self-reported procedures carried out by the trainees after completion of the training program

Secondary outcome measures
1. Postoperative complications in-hospital, self-reported by trainees in an online system. Measured continuously
2. Ability to name anatomical structures measured during training by trainers
3. Trainee and trainer impression of the model-based training, measured at the end of the

training by filling out a questionnaire
4. Number of attempts to passing score on the Operative Performance Rating System (OPRS), measured during training by the trainers
5. Time to passing score on the OPRS, measured during the training by the trainers (data course started - date of examination)
6. Score on the OPRS measured during training and noted in questionnaire by the trainers
7. Cost and cost-effectiveness of the training intervention - costs calculated with the perspective of the training program, effectiveness expressed as time to reach stability of operation time. Costs are measured at the time of the training intervention.

Overall study start date
01/03/2019

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Trainees in the CapaCare training program in Sierra Leone

Participant type(s)
Learner/student

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Unwillingness to participate and sign informed consent

Date of first enrolment
01/12/2022

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Masanga Hospital
Tonkolili District
Masanga
Sierra Leone
PO Box – 44 Magburaka

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Department of Molecular Medicine and Surgery
Karolinska University Hospital, L1:00
Stockholm
Sweden
17176
+46 (0)8 524 800 000
anders.franco-cereceda@ki.se

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 from the study will be published in one or more publication in peer reviewed journals. Results will also be presented at conferences.

Intention to publish date
01/06/2027

Individual participant data (IPD) sharing plan
Metadata will be openly accessible through Karolinska Institutet. Raw data can be made accessible through the primary investigator given appropriate ethical approvals are in place.

The name and email address of the investigator/body who should be contacted for access to the datasets: Jenny Löfgren, jenny.lofgren@ki.se.
The type of data that will be shared: de-identified data including number of attempts to reach proficiency, score on OPRS.
Dates of availability: after study completion.
Whether consent from participants was required and obtained: participants have given written informed consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			29/08/2023	No	No