# Simulation-based training for groin hernia repair in Sierra Leone

Submission date	<b>Recruitment status</b> Recruiting	<ul><li>Prospectively registered</li></ul>		
22/08/2023		[X] Protocol		
Registration date	Overall study status Ongoing  Condition category Digestive System	Statistical analysis plan		
01/09/2023		Results		
Last Edited		Individual participant data		
09/01/2025		[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**

https://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

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

# Protocol serial number

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

# Study type(s)

Other, Treatment

# 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(s)

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

# Key secondary outcome(s))

- 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.

#### Completion date

31/12/2027

# **Eligibility**

# Key inclusion criteria

Trainees in the CapaCare training program in Sierra Leone

# Participant type(s)

Learner/student

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

#### Sex

All

#### 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

#### **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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			29/08/2023	No	No