

Task sharing in paediatric inguinal hernia surgery

Submission date 28/06/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/07/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/07/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Current practice in groin hernia surgery for children in Uganda includes widely implemented task sharing as the surgeries are carried out by paediatric surgeons, general surgeons and medical doctors without formal surgical training after medical school and internship. The safety and effectiveness of this practice is not known. The study aims to assess the safety and effectiveness of task sharing in paediatric groin hernia surgery in Uganda.

Who can participate?

Children aged 1-12 years old, with reducible, primary, groin hernia and who are otherwise healthy (ASA 1-2) and where parents and child are willing to give informed consent and assent (children aged 8 years old and above).

What does the study involve?

The study involves a surgical procedure (inguinal hernia repair) performed by a consultant surgeon (non-paediatric surgeon) or a medical doctor (non-surgeon). It also involves interviews and physical examination before the surgery, at discharge from the hospital, after two weeks and after one year. Safety is the primary outcome and is defined as the occurrence of any postoperative complication at 2 weeks postoperatively. Secondary outcomes include hernia recurrence, patient satisfaction, chronic pain and quality of life one year postoperatively.

What are the possible benefits and risks of participating?

The main benefit of participating in the study is that the study participants will receive a groin hernia at no cost and will be followed up to detect any complications or recurrence. The study team will manage all unwanted outcomes after the surgery. Surgery is associated with certain risks but these risks are not elevated as a result of the study.

Where is the study run from?

The study is run from Uganda in three different hospitals - Soroti and Mubende Regional Referral Hospitals and Hope and Healing Centre outside Iganga town.

When is the study starting and how long is it expected to run for?

January 2020 to December 2030

Who is funding the study?

1. The Swedish Research Council
2. The Swedish Society of Medicine

Who is the main contact?

Dr Jenny Löfgren, jenny.lofgren@ki.se

Contact information

Type(s)

Public, Scientific, 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 University Hospital

L1:00

Stockholm

Sweden

19176

+46 (0)8 524 80000

jenny.lofgren@ki.se

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2

Study information

Scientific Title

Outcomes of paediatric inguinal hernia surgery performed by surgeons versus medical officers - a randomized controlled trial

Study objectives

Medical doctors who are not surgeons can perform paediatric inguinal hernia surgery with non-inferior results compared to surgeons.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 26/06/2024, Uganda Christian University Research and Ethics Committee (Plot 67-173, Bishop Tucker Road, Mukono, PO BOX 4, Uganda; +256 (0)312 350 800/880; info@ucu.ac.ug), ref: UCUREC-2024-829

Study design

Non-inferiority randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment, Safety

Participant information sheet

Health condition(s) or problem(s) studied

Inguinal hernia

Interventions

Inguinal hernia surgery will be carried out. The control arm will be operated on by specialist surgeons. The intervention arm will be operated on by medical doctors who are not surgeons but who have learnt this procedure on the job and who carry out hernia surgery in children as part of their work duties.

The randomization sequence will be generated online using blocks of 4, 6, and 8. The study number and randomization arm will be written on identical pieces of paper and sealed in opaque envelopes. At the beginning of each operation day, the operating list will be determined. Allocation to the control (surgeon) or intervention (MS) arm will be performed by a team member who will open the envelope when the next patient on the list is taken to the operating room. This person will not be involved in the operations or the generation of the operation list.

Intervention Type

Procedure/Surgery

Primary outcome measure

Occurrence of any postoperative complication assessed through patient/caregiver interview and physical examination at 2 weeks follow up

Secondary outcome measures

1. Patient satisfaction, level of pain (according to the Inguinal Pain Questionnaire score from 1-7), and quality of life according to EQ5D, all assessed through patient/caregiver interviews + physical examination by a medical doctor 2 weeks postoperatively
2. Recurrence, chronic pain according to IPQ (same as above), patient satisfaction ("Are you satisfied with the result of the operation?") and quality of life according to EQ5D assessed through patient /caregiver interview + physical examination by a medical doctor 1 year postoperatively
3. Costs and cost-effectiveness from the provider's perspective expressed as cost in USD per DALY averted at one timepoint

Overall study start date

01/01/2020

Completion date

31/12/2030

Eligibility

Key inclusion criteria

1. Child aged 1-12 years old
2. Primary reducible inguinal hernia
3. Otherwise healthy (ASA 1 and 2)
4. Willingness and ability of caregiver to give informed consent
5. Willingness and ability of child (8 years and above) to give informed assent

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

341

Key exclusion criteria

1. Previous surgery for inguinal hernia on the same side (i.e., recurrent hernia)
2. Comorbidity resulting in ASA classification 3 or higher
3. Irreducible/incarcerated hernia requiring emergency intervention
4. Caregiver/child not willing to participate

Date of first enrolment

16/07/2024

Date of final enrolment

31/12/2025

Locations

Countries of recruitment

Uganda

Study participating centre**Soroti Regoinal Referral Hospital**

Plot 1-7 Gweri Road

3-7 Moroto Road

Soroti

Uganda

PO Box 289

Study participating centre**Mubende Regional Referral Hospital**

Plot 6 Kakumiro Road

Mubende

Uganda

PO BOX 4

Study participating centre**Hope and Healing Center**

Kiwanyi 1, Nawandala Subcounty

Iganga

Uganda

PO Box 191

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 80000
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

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

Publication and dissemination plan

The researchers expect to publish several papers based on this research study. The first manuscript should be ready for submission to a medical journal towards the end of 2025.

Intention to publish date

01/06/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality. There is no plan to share patient-level data openly and there is no ethical approval to do so. If anyone desires to assess the data, they may do so after first obtaining ethical approval from the relevant bodies in Uganda. They can contact Dr Jenny Löfgren, jenny.lofgren@ki.se, with their interest who will guide them on who to contact at the ethics board that has approved the study in Uganda.

IPD sharing plan summary

Not expected to be made available