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Task sharing in paediatric inguinal hernia surgery

Submission date 28/06/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/07/2024	**Overall study status** Ongoing	
Last Edited 09/07/2024	**Condition category** Surgery	

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment, Safety

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 years

Upper age limit
12 years

Sex
All

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

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

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