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Training and task sharing in groin hernia surgery in men in Sierra Leone

Submission date
26/07/2017

Recruitment status
No longer recruiting

Registration date
23/08/2017

Overall study status
Completed

Last Edited
17/07/2023

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An inguinal hernia is a bulge in the groin area that causes pain, pressure and aching. Inguinal hernia repair is one of the most commonly performed surgical procedures, especially in sub-Saharan Africa. However, 200 million patients living with inguinal hernia do not receive necessary surgical care each year. In Uganda, the met need for inguinal hernia surgery is less than 1% per year. Using mesh to achieve a tension-free inguinal hernia repair significantly reduces the risk of hernia recurrence. However, most inguinal hernias are repaired using tissue techniques in resource-constrained settings. A commercial mesh costs over 100 USD and more than doubles the cost of a hernia repair in Uganda. Recent research has shown that a mosquito net, which comes at a fraction of the cost, is a safe and effective alternative to commercial mesh for elective inguinal hernia repair. In order for patients to benefit, this finding needs to be translated into practice. Major surgery is rarely performed by specialist surgeons in sub-Saharan Africa. Task-sharing of surgical procedures with non-surgeons is practiced in many African countries to various extents, depending on national policies. In sub-Saharan Africa, non-surgeon physicians and Non-Physician Clinicians (NPCs) commonly perform inguinal hernia repair. NPCs are mid-level health care providers who receive training to perform duties that medical doctors would normally do. In this case, they are trained to undertake a selected number of surgical procedures. Though there is some data to support the safety of inguinal hernia repair by NPCs in Tanzania, further research is needed to support this practice for mesh repair. The aim of this study is to evaluate if groin hernia repair in men can be trained to and performed by both medical officers and non-physician clinicians with similar outcomes and patient satisfaction.

Who can participate?
Adult men aged 18 and older who have a groin hernia

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their groin hernia repair performed by medical doctors. Those in the second group have their groin hernia repair performed by surgical non physician clinicians with three years of surgical training. After the surgery, they are free to move around but stay a few hours in hospital to make sure that all is well. Participants are followed up two weeks, one year and three years after their surgery to evaluate how well the surgery went and participant's satisfaction.

What are the possible benefits and risks of participating?
Participants receive a hernia repair at no cost. It is done using a surgical method that is standard in the west but that is currently not available to the majority in Sierra Leone. The surgeons (both medical doctors and non-physician clinicians) will have gone through a rigorous hands-on training programme and examination. Therefore these surgical providers will most likely be better equipped to perform these procedures than the average medical doctor in Sierra Leone. There are no direct risks in participating other than those risks normally associated with surgery.

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

When is the study starting and how long is it expected to run for?
March 2016 to December 2019

Who is funding the study?
Swedish Research Council, VR (Sweden)

Who is the main contact?
Dr Jenny Löfgren

Contact information

Type(s)
Scientific

Contact name
Dr Jenny Löfgren

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Inguinal hernia surgery in Sierra Leone: an implementation study of low cost anterior mesh repair performed by medical doctors and non-physician clinicians

Study objectives
Groin hernia repair in men can be performed by both medical officers and non physician clinicians with similar outcomes and patient satisfaction after standardised training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Sierra Leone Ethics and Scientific Review Committee, 22/05/2017

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Groin hernia in adult men

Interventions
Information about the study is spread in the community through different means; radio announcement, personal contacts, church and so on. Individuals with groin hernia are invited for an information meeting and screening after that. Those who are found to be eligible study participants are scheduled for surgery at a later date. They come to hospital the day before that date. They are examined once more by a senior surgeon to verify that the inclusion criteria are met. Thereafter, they are offered to be part of the study and sign/thumb print the informed consent. The operation list is prepared. Randomisation is done by a nurse using a computer-based program. It is done in blocks of 4 and 6.

Control group: Participants undergo groin hernia repair performed by medical doctors.
Intervention group: Participants undergo groin hernia repair performed by surgical non physician clinicians with three years of surgical training.

Both medical doctors and the surgical non clinician physicians undergo the same training before study start.

After the surgery, the patients are free to ambulate but stay a few hours in hospital to make sure that all is well. If the operation is done late in the day or if is a problem, they stay an extra night.

Follow up is done at two weeks, one year and three years. The Sierra Leonean PI is responsible for this. None of the surgeons performing the surgeries are involved in the follow up. The follow up consists of two parts: questionnaire based interview by a research assistant and physical examination by a medical doctor.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Recurrence is measured using a clinical examination at one year and three years postoperatively
2. Postoperative complication is measured using clinical examination at two weeks postoperatively

Secondary outcome measures
1. Chronic pain is measured using a validated tool (the Inguinal Pain Questionnaire) at one year and three years
2. Patient satisfaction is assessed through a questionnaire based interview at one year and three years
3. Health outcomes are assessed through a questionnaire based interview at baseline and at one year and three years

Overall study start date
15/03/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Primary, reducible groin hernia in adult males without significant comorbidities (ASA 1-2)
2. Aged 18 and older
3. Ability to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
250

Total final enrolment
230

Key exclusion criteria
1. Women and children
2. Recurrent hernia
3. Irreducible hernia
4. Comorbidity ASA 3 and above
5. Obvious alcohol or drug abuse
6. Known coagulation defect
7. Inability to give informed consent

Date of first enrolment
16/10/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Kamakwie Wesleyan Hospital
Kamakwie
Kamakwie
Sierra Leone
NA

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Solnavägen 1
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Sponsor type
Government

Website
www.vr.se

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Research council

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
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
28/02/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Jenny Löfgren, Department of Molecular Medicine and Surgery, Karolinska Institutet, Sweden at jenny.lofgren@ki.se OR jenny.loefgren@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/01/2021	12/01/2021	Yes	No
Results article		14/07/2023	17/07/2023	Yes	No