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Outcomes after low cost mesh repair of inguinal hernia performed by surgeons and non-surgeons in Ghana

Submission date
26/07/2017

Recruitment status
No longer recruiting

Registration date
21/08/2017

Overall study status
Completed

Last Edited
03/07/2019

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
A hernia occurs when an internal part of the body pushes through a weakness in the muscle or surrounding tissue wall. An inguinal hernia is the most common type of hernia and can appear as a swelling or lump in the groin or as an enlarged scrotum. 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 for 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. A recent study shows 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. Major surgery is rarely performed by qualified 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. The aim of this study is to assess the outcomes after low cost mesh repair of inguinal hernia performed by surgeons and non-surgeons in Ghana.

Who can participate?
Men aged 18 and above with a groin hernia

What does the study involve?
Surgeons and non-surgeon medical officers are trained to perform mesh hernia repair under local anaesthetic. Patients undergo mesh hernia repair surgery and are followed up after 2 weeks and after 1 and 3 years to assess whether the hernia comes back (recurrence), complications, pain and satisfaction. Cost and cost-effectiveness are calculated.

What are the possible benefits and risks of participating?
The participants receive a hernia mesh repair at a reduced cost. There are no risks in addition to the risks that are always associated with surgery.

Where is the study run from?
Ho Regional Referral Hospital (Ghana)

When is the study starting and how long is it expected to run for?
January 2016 to December 2021

Who is funding the study?
Swedish Research Council

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
Outcomes after low cost mesh repair of inguinal hernia performed by surgeons and non-surgeons in Ghana: an interventional prospective study

Study objectives

The hypothesis is that groin hernia repair can be performed by both surgeons and non-surgeon medical doctors with similar results in terms of recurrence, postoperative complications, and patient satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ghana Health Service Ethics Review Committee (GHS-ERC), 01/10/2016, ref: GHS-ERC:01/10/16
2. University of Pennsylvania, Institutional Review Board, ref: 825122

Study design
Interventional prospective study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Groin hernia

Interventions
Surgeons and non-surgeon medical officers will be trained to perform mesh hernia repair under local anaesthesia. After completion of the training, patients will be included into the study. They will be followed up after two weeks, after one and three years. Follow up will specifically include evaluation of recurrence, postoperative complications, chronic pain and patient satisfaction. Cost and cost-effectiveness will be calculated.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Recurrence, measured by clinical examination at 3 years postoperatively
2. Postoperative complications, measured by clinical examination at 2 weeks postoperatively

Secondary outcome measures
1. Chronic pain, measured using a validated tool (the Inguinal Pain Questionnaire) at 3 years
2. Patient satisfaction, assessed through a questionnaire-based interview at 3 years
3. Health outcome, assessed through a questionnaire-based interview at inclusion and at 3 years

Overall study start date
14/01/2016

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Adult male with primary, reducible, groin hernia
2. Healthy (ASA 1 and 2)
3. Ability to give informed consent
4. Adults (aged 18 and above), no upper age limit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
250

Total final enrolment
242

Key exclusion criteria
1. Women
2. Children
3. Recurrent hernia
4. Inability to give informed consent
5. Obvious alcohol or substance abuse
6. Known coagulopathy

Date of first enrolment
15/02/2017

Date of final enrolment
15/10/2017

Locations

Countries of recruitment

Ghana

Study participating centre
Ho Regional Referral Hospital
Ho
Ghana
-

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Solnavägen 1, Solna
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Sponsor type
University/education

Website
www.li.se

ROR
https://ror.org/04hmgwg30

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
Planned publication in a high-impact peer reviewed journal. More than one paper is planned, and the first will be following the 1-year reviews.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jenny Löfgren.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019	03/07/2019	Yes	No