

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/07/2019	Condition category Digestive System	<input type="checkbox"/> 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

ORCID ID
<http://orcid.org/0000-0001-5884-0369>

Contact details
Institutionen för molekylär medicin och kirurgi
Karolinska Institutet
Karolinska Universitetssjukhuset Solna (L1:00)
Stockholm
Sweden
17176

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
Stockholm
Sweden
17177
+46 (0)8 524 800 00
info@ki.se

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