ISRCTN20596933 https://doi.org/10.1186/ISRCTN20596933

Inguinal hernias - epidemiology, mosquito nets and cost effectiveness

Submission date	Recruitment status	[_] Prospectively registered
09/01/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/02/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/04/2025	Digestive System	

Plain English summary of protocol

Background and study aims
An inguinal hernia occurs when fatty tissue or a part of the bowel pokes through into the groin. They are usually painful and may occasionally even cause death. Surgical repair of inguinal hernias is one of the most common procedures in sub-Saharan Africa. In high-income countries, the repair is usually done with a plastic mesh. It has been proven many times to be vastly superior to non-mesh repair methods. In low- and middle-income countries, these meshes are almost always too expensive for most people, who are therefore treated by outdated methods with a poor outcome. The use of locally available sterilized mosquito nets in hernia repair appears to be a promising alternative. The aim of this study is to find out whether the use of commercial mesh and mosquito nets are comparable in terms of outcome.

Who can participate?
Men aged over 18 with an inguinal hernia.

What does the study involve?
Participants are randomly allocated to have a hernia repair using either a standard commercial mesh or a sterilized mosquito net of similar size. They are followed for at least a year to see if there is any difference in complications, pain and recurrence between the groups. We also calculate the cost-effectiveness of these two forms of hernia repair.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Karolinska Institute (Sweden)

When is the study starting and how long is it expected to run for?
February 2012 to June 2014

Who is funding the study?
Swedish Medical Society, Karolinska Institute, Golje Foundation and Capio Foundation (Sweden).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2012/1

Study information

Scientific Title
Inguinal Hernia Surgery in Uganda [IHSIU) - a randomized clinical trial comparing commercial mesh and mosquito net in the Lichtenstein Repair of Uncomplicated Inguinal Hernia in the Iganga-Mayuge demographic surveillance site in Uganda

Acronym
IHSIU

Study objectives
In open, surgical repair of primary inguinal hernias, the use of commercial mesh and mosquito nets are comparable in terms postoperative outcome and different only with regard to cost.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Makerere University, Kampala, Uganda, 05/10/2011, ref: SBSC 006

Study design
Double-blind randomized controlled clinical 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Primary inguinal hernias

Interventions
Patients will be randomized to have a hernia repair using either a standard commercial mesh or a sterilized mosquito net of similar size

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Postoperative complications
2. Postoperative pain
3. Hernia recurrence
4. Cost-effectiveness

Secondary outcome measures
Quality of life

Overall study start date
06/02/2012

Completion date
27/06/2014

Eligibility

Key inclusion criteria

1. Age > 18 years
2. Male
3. Reducible, unilateral, primary, inguinal hernia
4. The patient accepts participation and gives informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
380

Key exclusion criteria
1. Female
2. Recurrent hernia
3. Femoral hernia
4. Ongoing anticoagulant medication
5. Current drug abuse
6. ASA group 3 and above

Date of first enrolment
06/02/2012

Date of final enrolment
27/06/2014

Locations

Countries of recruitment
Sweden

Uganda

Study participating centre
Karolinska Institute
Stockholm
Sweden
112 81

Sponsor information

Organisation
Swedish Medical Society (Sweden)

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Sponsor type
Research organisation

Website
http://www.slf.se/Info-in-English/

ROR
https://ror.org/016ks4x90

Funder(s)

Funder type
Research organisation

Funder Name
Swedish Medical Society (Sweden)

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Sweden

Funder Name
Golje Foundation (Sweden)

Funder Name
Capio Foundation (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/01/2016		Yes	No
Results article	cost-effectiveness results	01/05/2017		Yes	No