

Inguinal hernias - epidemiology, mosquito nets and cost effectiveness

Submission date 09/01/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/04/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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and middle-income countries, these meshes are almost always too expensive for most people, who are therefore treated by outdated methods with a poor outcome.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?

Dr Andreas Wladis
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Quality of life

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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)

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

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