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Treatment of hernias in Cameroon with cheap nets using the small incision technique

Submission date	Recruitment status	[_] Prospectively registered
05/05/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/05/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/06/2023	Digestive System	

Plain English summary of protocol

Background and study aims
Adverse economic conditions often prevent the widespread implementation of modern surgical techniques in third-world countries such as those in Sub-Sahara Africa. The aim of the study is to demonstrate that a modern technique (laparoscopic totally-extraperitoneal inguinal hernioplasty) can safely be performed at a significantly lower cost by using inexpensive mesh material (mosquito mesh).

Who can participate?
Patients aged over 16 with reductible primary or recurrent inguinal hernia

What does the study involve?
Participants are randomly allocated to undergo laparoscopic totally-extraperitoneal inguinal hernioplasty using either conventional mesh or mosquito mesh. Operative time is measured as the duration between the first incision and placement of the last skin stitch.

What are the possible benefits and risks of participating?
Participants receive free hernia treatment. The risks include infection of the mesh, the normal risks of any operation, and in rare cases rejection of mesh.

Where is the study run from?
Douala University Hospital Gynecology, Obstetric and Pediatric and two affiliated centers, Ayos Regional Hospital and Edéa Regional Hospital (Cameroon)

When is the study starting and how long is it expected to run for?
December 2017 to November 2020

Who is funding the study?
Royal Belgian Academy for Higher Education Research (Belgium)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PFS/ARES 2016

Study information

Scientific Title
Laparoscopic approach to the treatment of hernias by prosthesis in poor and low-income countries: the feasibility, clinical effectiveness, and socio-economic aspects of adult patients presenting with primary inguinal hernia treated by totally-extraperitoneal inguinal hernioplasty, comparing implantation of sterilized mosquito mesh with conventional polypropylene mesh

Study objectives
To demonstrate that a modern technique (laparoscopic totally-extraperitoneal inguinal hernioplasty [TEP]) can safely be performed at a significantly lower cost by using inexpensive mesh material.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/09/2018, institutional committee for research on human health CEI-HGOPED (BP 7270, Douala, Cameroon; +237 (0)233504302; cei.hgoped@gmail.com), ref: 2018/0042/HGOPED /DG/CEI
Approved 11/08/2020, institutional ethics committee for research on human health CEI-UDo (Douala University Cameroon, BP 2701, Douala Cameroon; +237 (0)680359835/+237 (0) 695393550; cei@univ-douala.com), ref: 2324CEI-Do/08/2020/T

Primary study design

Interventional

Study design
Single-centre prospective randomized study

Study type(s)
Treatment

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

Interventions
All patients are examined preoperatively by at least one of the authors and checked as per routine by a senior anesthesiologist. After informed consent is obtained, both for surgery and for inclusion in the study, the patients are scheduled for surgery, described in the consent form as laparoscopic TEP unilateral/bilateral inguinal hernioplasty (the study protocol includes systematic exploration of the contralateral side, even in the absence of clear signs of contralateral hernia). In case of bilateral hernia, the type of mesh used is identical on both sides. The interventions are free of charge for patients and are part of the cooperation between the “Université Libre” of Brussels and the University of Douala funded by the (ARES/Belgium) to train Cameroonian surgeons in minimally-invasive surgery (PFS2016).

Randomization and blinding:
Each day of operation, an even number of patients (n=6) is programmed per day. In the absence of the surgeon and the patients, an equal number of prostheses are prepared by the nurse, half of them in mosquito mesh (MM, code A) and half in conventional mesh (CM, code B). In order to anticipate the possibility of bilateral hernias, three times two prosthesis of the same type are inserted in an envelope and an external doctor (not involved in the study) arbitrarily attributes a number of 1 to 6 to each envelope. Patients and surgeons are unaware of the selection and processing of the types of prostheses. Each patient draws one number between 1 to 6 before entering the operating room. The corresponding prosthesis is handed to the surgeon in the operating room after dissection had been completed. The name of the patient and the corresponding code of the received prosthesis are mentioned in a special register. The type of prosthesis however is not mentioned in the operative report and remains unknown to the patient and nursing team throughout the postoperative period and follow-up.

Procedure:
The patient is placed supine, arms alongside the body, and general anesthesia with endotracheal intubation initiated as per routine. The patient is prepared and draped and the preperitoneal space entered and the preperitoneal inguinal dissection carried out as described by others. After full dissection of the retro-inguinal space by the surgeon, a sterile mesh is provided from the operating theatre supply, and the code on the drawn envelope number is recorded by the circulating nurse in the “ad hoc” registry. As mentioned in the previous paragraph, in the case of bilateral hernia (either foreseen or unexpected) the mesh used for the contralateral side is automatically of the same material as the opposite side. In case of unilateral hernia, the superfluous mesh is discarded.

Registered information includes demographics, occupation, and hernia status as recorded during the operation. Possible early complications (within 30 postoperative days) are registered in the patient's chart as registered the day of patient’s discharge, after 15 days, at 3 months and every six months, and relevant data is recorded by a staff member who is unaware of the material used

for hernia repair, yet is informed that the patient is part of an ongoing clinical trial. At each occasion the patient is interrogated and physically examined to rule out the presence of complications, such as hematoma, infection, seroma, hernia recurrence or abnormal (neural) pain. Data are kept in the patient's chart. Conclusive assessment is performed by analysis of the patient's chart and confrontation with the labelling in the ad hoc register. Finally, after the conclusion of the clinical evaluation, a final financial balance is made and registered. Statistical analysis is performed using IBM SPSS Statistics 20.0 software. Data, when distributed normally, are presented as mean ± standard deviation (range) or, in case of non-normal distribution, as median (interquartile range [IQR]). For qualitative variables, a c2 test is used. When comparing means of quantitative variables, a Student’s t-test is used. A p-value lower than 0.050 is considered statistically significant.

Operative time is measured as the duration between the first incision and placement of the last skin stitch. After the conclusion of the procedure, the patient is taken to the recovery room and subsequently to the ward for an overnight stay, followed by discharge from the hospital the following day. Again, no mention is made of the type of implanted material in the patient’s chart, nor verbally to the patient. Hospital stay is recorded as the duration between the start of the operation and the time of discharge.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Operating time (from first skin incision to closure) measured using medical notes (anesthesia sheet) at the end of surgery

Key secondary outcome(s)
1. Conversion to open surgery during laparoscopic procedure, measured using medical notes (desaturation, major bleeding, camera failure, difficult dissection, very low blood pressure) during surgery
2. Incidence of seroma measured by physical examination on day 1 to day 90 postoperative
3. Incidence of hematoma measured by physical examination on day 1 to day 30 postoperative
4. Reoperation measured using medical notes (infection, reject of mesh, major bleeding, recurrence, bowel obstruction) on day 1 to month 30 postoperative relative to the primary operation
5. Infection measured using physical examination, temperature over 38°C, blood tests, on day 1 to month 30 postoperative relative to the primary operation
6. Recurrence measured using physical examination on day 1 to month 30 postoperative

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. Adult (aged >16 years) native patients
2. Presenting at one of the participating hospitals between October 2018 and March 2020
3. Suffering from reducible primary or recurrent inguinal hernia, either uni- or bilateral

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. History of laparotomy or retroperitoneal surgery
2. Strangulated or irreductible inguinal hernia
3. Inguinoscrotal hernia
4. Non-inguinal hernia
5. Participant who refused consent to study
6. Participant deemed unfit to undergo general anesthesia

Date of first enrolment
01/10/2018

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
Cameroon

Study participating centre
Gyneco Obstetric Pediatric Hospital (HGOPED)
Douala
Douala
Cameroon
BP 7270

Sponsor information

Organisation

Académie de Recherche de l'Enseignement Supérieur Belgique

Funder(s)

Funder type
Government

Funder Name
Higher Education Research Academy (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Essola Basile (basile.essola@ulb.be)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/03/2021	07/05/2021	Yes	No
Results article		31/01/2022	13/06/2023	Yes	No
Protocol file			11/05/2021	No	No