ISRCTN21578845 https://doi.org/10.1186/ISRCTN21578845

Quality of life after inguinal hernia repair

Submission date
08/10/2017

Recruitment status
No longer recruiting

Registration date
23/12/2017

Overall study status
Completed

Last Edited
01/12/2017

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A hernia occurs when a part of the body on the inside pushes through the muscle or tissue weak spots. An inguinal hernia occurs in the groin area as a swelling or lump. Hernias often require surgery that puts a mesh on the muscle or tissue to reinforce it. There are different types of mesh include prolene or progrip mesh.There are not enough studies to provide the sufficient information on how inguinal hernia repair improves the quality of life. The aim of this study is to appreciate the postoperative chronic pain and the quality of life in patients who undergo plastic repair with either progrip or prolene mesh and as secondary approach to study the possible postoperative complications.

Who can participate?
Male patients aged 18-75 years old with inguinal hernia.

What does the study involve?
The patients are randomly allocated to one of two groups. Those in the first group have progrip used for their surgery. Those in the second group have prolene used for their surgery. The techniques and surgeries are the same for both groups. Participants are followed up with telephone calls at six months to assess their pain and quality of life.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
Agios Dimitrios General Hospital (Greece)

When is the study starting and how long is it expected to run for?
February 2016 to May 2018

Who is funding the study?
Agios Dimitrios General Hospital (Greece)

Who is the main contact?
Dr Anastasios Katsourakis (Scientific)
tasoskatsourakis@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Anastasios Katsourakis

ORCID ID
http://orcid.org/0000-0002-5151-9449

Contact details
Agios Dimitrios General Hospital
2 Elenis Zografou
Thessaloniki
Greece
GR-54634
+30 2313 322 178
tasoskatsourakis@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01/hernia/09.2017

Study information

Scientific Title
Quality of life After Inguinal Hernia Repair: progrip vs prolene a randomised controlled trial

Acronym
QAIHR

Study objectives
Does the inguinal hernia repair improve the quality of patients' life?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific Council, Agios Dimitrios General Hospital of Greece, 16/01/2017, ref: 8th/ Topic ΕΗΔ 2th/08.08.2017

Study design
Interventional single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files (in Greek)

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

Interventions
Five consultants from the Surgical Department of “Agios Dimitrios Hospital” participated in the study, operated one patient at a time consequently, with both techniques, according to the randomization and watched over the postoperative period for six months. During the participants admission to the hospital, and after having read and signed the consent form for participation in the study, patients answered a questionnaire related to his medical and family history. Each patient was operated and participated to the study for the first episode or inguinal hernia. Participants are randomly allocated using closed enveloped to one 2 groups: progrip vs prolene group.

Participants undergo inguinal hernia repair using the treatment they were randomised to have: progrip or prolene mainly). ProGrip is a macroporous polyester mesh with resorbable polylactic acid (PLA) micro-grips on one side of the mesh, allowing its safe placement The fact that it is not necessary the use of sutures, fibrin glue or tacks in order to secure the mesh, reduces the operative time. On the other hand, polypropylene mesh is a lightweight, macroporous mesh which requires multiple sutures.

The surgical techniques that were used for both meshes were held with either general, regional or local anesthesia, according to the indications of the anesthesiologist or the demands of the patient. Lichtenstein operation was performed for polypropylene mesh. Through a 7 cm incision, the subcutaneous fat along the line of the incision and the Scarpafascia down to the external oblique aponeurosis were opened. The external inguinal ring and the lower border of the inguinal ligament were recognized. Then, we divided external oblique aponeurosis from the external ring laterally for up to 5 cm, safeguarding the ilioinguinal nerve. The superior and inferior flaps of the external oblique aponeurosis were mobilized, safeguarding the iliohypogastric nerve, in order to expose the underlying structures. Mobilization of the spermatic cord, along with the cremaster, including the ilioinguinal nerve, the genitofemoral nerve, and the spermatic vessels was held. All of these structures were encircled in a Penrose drain. We opened the coverings of the spermatic cord and identified and isolated the hernia sac, which then, was inverted, divided, resected or ligated, as indicated. We placed and fixed the

mesh to the edges of the defect or weakness in the posterior wall of the inguinal canal to create a new artificial internal ring, taking care to allow some laxity to compensate for increased intra-abdominal pressure when the patient stands. Finally, we gently pulled of the testes back down to their normal scrotal position and closed the spermatic cord layers, the external oblique aponeurosis, the subcutaneous tissue, and the skin.

The surgical technique for Progrip mesh is similar to Lichtenstein operation. After having dissected the hernia sac, we place the mesh. The self – gripping flap of the mesh is then opened and closed around the cord outside the operating area in order to avoid any untimely side by side placement. The mesh is then placed carefully to its final position. Its fixation is performed with one single suture at the pubic tubercle. No additional fixation suture is required. In both techniques we preserved and safeguarded all the nerves.

The day after the surgery, patients without postoperative complications return home. Cleaning and observation of the surgical wound is performed every two days, until the removal of the stitches, the eighth day. Participants are fill out SF36 to evaluate the pain through telephone interview the first and the sixth month after the surgery. In case of a complication, they were readmitting to the hospital for examination. No surgical technique was modified or individualized in any of the 200 patients.

Intervention Type
Mixed

Primary outcome measure
1. Pain in measured using the Visual Analogue Scale Core (VAS) at one and six months
2. Quality of life is mesaured using the questionnaire SF36 at one and six months

Secondary outcome measures
Immediate and long-term postoperative complications are measured using the medical records when they occur and at six months.

Overall study start date
01/02/2016

Completion date
30/05/2018

Eligibility

Key inclusion criteria
1. Male patients with inguinal hernia, fit to surgery.
2. Aged 18-75 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
75 Years

Sex
Male

Target number of participants
200 patients

Key exclusion criteria
1. Relapse
2. Bilateral inguinal hernia
3. Strangulated inguinal hernia
4. Female patients
5. Inguinoscrotal hernia
6. Laparoscopic repair
7. Other alongside surgery

Date of first enrolment
01/01/2017

Date of final enrolment
01/01/2018

Locations

Countries of recruitment
Greece

Study participating centre
Agios Dimitrios General Hospital of Greece
2 Elenis Zografou
Thessaloniki
Greece
GR-54634

Sponsor information

Organisation
Agios Dimitrios General Hospital scientific committee

Sponsor details

2 Elenis Zografou Street
Thessaloniki
Greece
GR-54634
+30 2313 322 100/ 178
tasoskatsourakis@hotmail.com

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Agios Dimitrios General Hospital

Results and Publications

Publication and dissemination plan
Intentions to publish the results immediately after the recruitment of statistical significant number of patients after the statistical analysis. The study protocol and the statistical analysis plan will be available.

Intention to publish date
30/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Anastasion Katsourakiw, MD, PhD- tasoskatsourakis@hotmail.com

IPD sharing plan summary
Available on request