Comparison of Cousin Biotech® Adhesix* versus conventional mesh in open anterior inguinal hernia repair: a Multi-centre, Randomised, Double-blinded, Controlled Clinical Trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Interventional

Summary

ID

NL-OMON38042

Source
ToetsingOnline

Brief title
Self-adhering mesh versus conventional mesh in inguinal hernia repair.

Condition

- Abdominal hernias and other abdominal wall conditions

Synonym
inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Maastricht Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: inguinal hernia, postoperative pain, self-adhering mesh

Outcome measures

Primary outcome

The primary outcome measure is postoperative pain as reported during the first month with a special emphasis on analgesics use and pain experienced in the first two postoperative weeks.

Secondary outcome

Time to return to work

Time to return to normal daily activity

Time to first pain-free sexual intercourse

Quality of Life measurement using General SF-36 Questionaire and disease specific Carolina's comfort Scale.

Late postoperative pain

Operation length

Postoperative complications (e.g. infection, recurrence).

Study description

Background summary

Inguinal hernia repair coincides with a high rate of postoperative pain, extending to over a year in 10-20% of patients. Although this is of major concern, early postoperative pain also has an important impact on patients and

their ability to regain normal work and activities. Since inguinal hernia repair is the most frequently performed operation worldwide, a small reduction in loss of workdays can already have significant impact on financial issues. As for the origin of the pain, it might be the result of local inflammation caused by the mesh material, but also by nerve entrapment due to fixation techniques. The development of a new mesh which enables sutureless fixation, Cousin Biotech® Adhesix*, may overcome pain related to fixation techniques used in the open hernia repair procedure according to Lichtenstein. Furthermore, the Cousin Biotech® Adhesix* mesh has already been in use in our institutions and surgeons familiarized themselves with the application.

Study objective

We would like to conduct a multicentre randomised controlled clinical trial to compare the difference in early postoperative pain after unilateral primary inguinal hernia repair in males. The procedures will be performed in day surgery. Early postoperative pain is defined as the pain during the first month, with a special interest in the first two weeks. In addition, we want to measure the possible benefit in terms of time to return to work, daily activities, quality of life, operation length, complications and long term postoperative pain.

Study design

Multi-centre, randomised, double blinded, controlled clinical trial.

Intervention

Surgical inguinal hernia repair, with placement of a surgical mesh.

Study burden and risks

Inguinal hernia repair at this moment is the most performed operation in humans. Since this study investigates the differences between two commercially available and widely used meshes, using the well-known modified Lichtenstein technique, there are no additional risks besides the standard risk of complications associated with the open anterior inguinal hernia repair. As an extra effort, patients will have to fill out a logbook at home during the first 4 weeks and will visit the outpatient clinic at 1 week, 6 weeks and 12 months after surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male
Primary, unilateral inguinal hernia
Age >=18 years
ASA-score I-III
Signed informed consent
Elective surgery

Exclusion criteria

Female
Bilateral and/or recurrent inguinal hernia
Femoral or scrotal hernia
Vasectomy
Chronic use of pain medication
Symptomatic acute hernia (i.e. bowel obstruction, incarceration, strangulation, peritonitis or

perforation of bowel contents)
ASA-score IV or above
Incapacitated adult or no signed informed consent
Patient is unable to speak Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2011
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	03-09-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36322.068.11
Other	volgt