Tilburg double blind randomised controlled trial comparing inguinal hernia correction with anterior approach via Lichtenstein or Polysoft.

Published: 15-10-2007
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To compare postoperative pain after anterior inguinal repair with mesh according to Lichtenstein or open repair with Polysoft® mesh

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31037

Source
ToetsingOnline

Brief title
The Tulip trial

Condition

- Soft tissue therapeutic procedures

Synonym
hernia ventralis, inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: door maatschap chirurgie St Elisabeth

ziekenhuis zelf

Intervention

Keyword: anterior approach, inguinal hernia, pain

Outcome measures

Primary outcome

Primary endpoint will be difference in pain and chronic pain postoperatively.

Secondary outcome

Secondary endpoints are length of operation, postoperative complications,

length of hospital stay, return to daily activities and work, costefficiency

analysis, health related quality of life and recurrence.

Study description

Background summary

Chronic pain is a postoperative complication in inguinal repair. Anterior open approach with mesh is advocated by the Dutch Surgeon*s College. Preliminary experience with a lightweight mesh placed in the preperitoneal space showed good results and less postoperative pain.

Study objective

To compare postoperative pain after anterior inguinal repair with mesh according to Lichtenstein or open repair with Polysoft® mesh

Study design

We aim to perform a double centre, double blind randomised controlled trial to compare both methods.

Intervention

One group will be operated via an anterior approach with mesh placement according to Lichtenstein, the other group will be operated via an anterior

approach with Polysoft® mesh placement in the preperitoneal space.

Study burden and risks

Patients will be asked to fill in questionnaires. Outpatient clinic check ups will be scheduled at two weeks, three months and one year postoperatively.

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

Primary groin hernia unilaterally, Age > 18 years. ASA classification 1-3, Signed informed consent letter

Exclusion criteria

Recurrent hernia, Age <18or >80, Scrotal hernia*s , ASA 4/5, Acute incarcerated inguinal hernias, Psychiatric disease or other reason making follow up of filling in questionnaires unreliable.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2008
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Polysoft mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-10-2007
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL16781.008.07