The HELI pilot: clinical research to investigate the possibility of fixation of the polypropylene mesh with autologous growth factor fibrin glue in hernia inguinalis surgery.

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Using AGW gives a good fixation of the polypropylene mesh in hernia inguinalis surgery and will not lead to a higher recurrence rate. The maximum acceptable recurrence rate is 10% after 3 months.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON30095

Source
ToetsingOnline

Brief title
HELI pilot

Condition

- Connective tissue disorders (excl congenital)
- Soft tissue therapeutic procedures

Synonym
hernia

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharinaziekenhuis

Intervention

Keyword: chronic pain, fibrin glue, fixation, Lichtenstein

Outcome measures

Primary outcome

Recurrence rate (max 10%)

Secondary outcome

Pain score day 1, 14 after surgery

Pain score 3 months after surgery

Study description

Background summary

Hernia inguinalis is a rather common disorder mostly seen at men. Since several years, the use of a polypropylene mesh during hernia surgery has become standard, since it results in reducing the recurrence rate significantly.
With reducing the recurrence rate, the frequent appearance of chronic pain after the surgery has become more prominent and therefor at this point the biggest concern of this type of surgery. One of the possible causes is damage of the local nerves by the use of sutures for fixation of the mesh. Therefor, alternatives for fixation of the mesh are being investigated.
Several publications indicate Tissuecol (a commercial fibrin glue) to be a promising option for fixation od the mesh at which the chronic pain indeed was diminidhed and the recurrence rate still was low. The published studies are rather small and have a short follow-up. Upon that, Tissuecol has some disadvantages related to the fact that it contains foreign components (e.g. allergy, coagulation disturbances, costs). Autologous growth factors fibrin glue (AGW) seems to be an attractive alternative. AGW is being prepared out of blood from the patient and contains fibrinogen (taking care of the acute fixation of the mesh) and autologous growth factors (support ingrowth of the mesh and therefor the definite fixation). AGW is being used successfully for several other medical applications concerning fixation.

In the near future, a clinical trial will be performed, comparing chronic pain post operatively between patients with fixation of the mesh by sutures and patients with fixation of the mesh by AGW. Before a bigger group of patients can be included in such a trial, it must be indisputable that AGW can provide indeed the needed fixation of the mesh, with the normal recurrence rate. This item is being investigated in the protocol HELI-pilot, at which in total 20 patiënts with a hernia inguinalis will be operated upon using AGW for fixation of the mesh.
The most important outcome parameter is the recurrence rate. The maximum acceptabel recurrence rate is 10% after 3 months. Secundary, the occurrence of pain after the operation will be scored.

Study objective

Using AGW gives a good fixation of the polypropylene mesh in hernia inguinalis surgery and will not lead to a higher recurrence rate. The maximum acceptable recurrence rate is 10% after 3 months.

Study design

• Patiënts who meet the inclusion criteria are informed on the study at the outpatients' clinic and after signing the informed consent patiënts are assigned to the waiting list.
• Preoperatively blood samples are taken and the AGW is prepared.
• The operations are performing following the protocol (appendix B). One of the surgeons from the project team will be present at the operation to diminisg the chance that recurrences occurr due to methodological reasons.
• All patiënts will be seen (post operatively) at the outpatients' clinic by one of the surgeons from the project team.
• Patiënts will visit the outpatients' clinic after 2 weeks and after 3 months for cchekcup. With more than 2 recurrences after 3 months, the pilot study is judged unsuccessful and will be stopped immediately.
• Patiënts complete a short questionnaire on day 1 after surgery, day 14 after surgery and 3 months after surgery.

Intervention

Surgery of the hernia inguinalis following the Lichtenstein procedure, at which AGW is used for fixation of the macroporous polypropyleen mesh.

Study burden and risks

• Pre-operatively two samples of 53 ml blood is taken for preparation of the AGW.
• One surplus visit at the outpatients' clinic after 2 weeks (to detect properly early recurrences).

• The visit to the outpatients' clinic after 3 months is a standard procedure after hernia inguinalis 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

primary unilateral hernia inguinalis
male
at least 18 years of age
sufficient knowledge of the Dutch language
competent to make their own decisions
ASA-1 or ASA-2
informed consent is signed

Exclusion criteria

female
male with scrotal hernia
age under 18
incompetent of making decisions
lack of understanding the Dutch language
previous groin surgery
ASA-3 or ASA-4

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	04-01-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL13737.060.06