ISRCTN93798494 https://doi.org/10.1186/ISRCTN93798494

Lichtenstein technique versus transinguinal preperitoneal mesh prosthesis (TIPP): less chronic pain?

Submission date	Recruitment status	[_] Prospectively registered
12/11/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2014	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.liesbreukcentrumbrabant.nl

Contact information

Type(s)
Scientific

Contact name
Mr Giel G Koning

Contact details
St Elisabeth Hospital
Department of Surgery
Hilvarenbeekseweg 60
Tilburg
Netherlands
5022 GC

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The Tilburg double-blind randomised controlled trial comparing inguinal hernia repair according to Lichtenstein and the transinguinal preperitoneal technique

Acronym
TULIP

Study objectives
The transinguinal preperitoneal (TIPP) technique will show reduction of chronic pain compared to the Lichtenstein technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical Ethical Testing Committee (METC) of St Elisabeth Hospital and TweeSteden Hospital gave approval on the 28th November 2007 (ref: 0737)
2. Centrale Commissie Mensgebonden Onderzoek (CCMO) Central Committee for Research Involving Human Subjects gave approval on the 24th September 2007 (ref: NL16781.008.07)

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Unilateral groin hernia

Interventions
All patients will be operated via anterior approach with a skin incision two centimetres above the Poupart ligament.

In half of the study population the groin hernia will be corrected according to the Lichtenstein technique. This is the reference treatment advised by the Dutch Society of Surgeons. The Lichtenstein technique will be attempted to present-day insights; a soft mesh will be used instead of the polypropylene mesh.

The other 150 inguinal hernia patients will be operated by the transinguinal preperitoneal (TIPP) technique with Polysoft® mesh. In this technique an inguinal incision 4 - 5 cm long is made, the external oblique aponeurosis is divided and the cord lifted on a tape. The cremaster muscle is divided around the internal orifice, but not stripped, and the sac is dissected. The technique of placement of the Polysoft® mesh into the preperitoneal space adapts anatomically to the type of hernia.

Type of hernia will be assessed using the European Hernia Society groin hernia classification. This classification is simple and easy to remember. The size of the hernia orifice is registered as 1 (less than or equal to 1 finger), 2 (1 - 2 fingers) or 3 (greater than or equal to 3 fingers) accompanied with L (lateral), M (medial) or F (femoral). All of the hernias will be primary (P) classified according to the inclusion criteria so recurrent (R) will not be assessed in our population.

In indirect hernias high dissection of the sac is performed and the sac is thus reduced in the preperitoneal space (PPS) through the internal ring. Blunt dissection is carried out in the PPS, through the internal orifice and is then extended deep to epigastric vessels and transverse fascia, in the direction of the pubic spine, beyond its level. The patch is introduced in the PPS via the internal orifice. In regional or local anaesthesia asking the patient to strain allows correct anatomical spreading of the mesh, which is applied to the deep aspect of the fascia. The assessment is done by asking the patient to strain and to cough. External oblique aponeurosis was repaired superficial to the cord to restore the normal anatomy.

In direct hernias, after division of the cremaster so as to check the internal orifice for an indirect sac, the transverse fascia is divided circularly around the hernia bulge and the sac is reduced. Blunt dissection is carried out in the PPS, medially in the direction of the pubic spine and laterally behind the epigastric vessels in direction of the iliac spine. The patch is introduced through the transverse fascia opening and spread in the PPS so as to cover all the weak inguinal area. When an indirect sac, even if it is small, is associated to the direct one, both sacs are dissected and reduced.

Total duration of treatment: 1 day in hospital on day of surgery. Outpatient department follow-up at 14 days, 3 months and 1 year post-operatively in both arms of trial.

Joint Sponsor:
TweeSteden Hospital (The Netherlands)
P.O. Box 90107
Tilburg
5000 LA
Netherlands

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Direct post-operative and chronic pain, measured post-operatively during hospital admission and at 14 days/3 months and one year; final measurement will be after follow up completion of the last patient in both groups.

Secondary outcome measures
1. Operation time
2. Post-operative complications
3. Hospital stay
4. Return to daily activities (e.g. work)
5. Recurrence

Measured post-operatively during hospital admission and at 14 days/3 months and one year; final measurement will be after follow up completion of the last patient in both groups.

Overall study start date
01/12/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Primary unilateral groin hernia
2. Aged greater than 18 years, either sex
3. American Society of Anaesthesiologists (ASA) classification 1 - 3
4. Signed informed consent letter

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300 patients

Key exclusion criteria
1. Recurrent hernia
2. Aged less than 18 or greater than 80 years
3. Scrotal hernia(s)

4. ASA classification greater than 4
5. Acute incarcerated inguinal hernia(s)
6. Psychiatric disease or other reason making follow-up or questionnaires unreliable

Date of first enrolment
01/12/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
St Elisabeth Hospital
Tilburg
Netherlands
5022 GC

Sponsor information

Organisation
St Elisabeth Hospital (Netherlands)

Sponsor details
Hilvarenbeekseweg 60
Tilburg
Netherlands
5022 GC
g.koning@elisabeth.nl

Sponsor type
Hospital/treatment centre

Website
http://www.elisabeth.nl

ROR
https://ror.org/04gpfvy81

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Elisabeth Hospital (Netherlands)

Funder Name
TweeSteden Hospital (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/09/2009		Yes	No
Results article	results	01/06/2013		Yes	No