ISRCTN96288558 https://doi.org/10.1186/ISRCTN96288558

A prospective randomised controlled trial of Vypro II and TiMesh in inguinal hernia repair using the total extraperitoneal endoscopic approach

Submission date 13/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/11/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/09/2009	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
No difference in inguinal pain and discomfort between TiMesh and Vypro II used in inguinal hernia repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Total endoscopic extraperitoneal hernia repair with either TiMesh or Vypro II.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Inguinal pain and discomfort at 6 weeks and 2 years.

Secondary outcome measures

1. Hernia recurrence
2. Complications
3. Quality of life

Overall study start date
01/01/2004

Completion date
01/06/2006

Eligibility

Key inclusion criteria
1. Male gender
2. Primary bilateral hernia
3. Recurrent unilateral hernia
4. Primary unilateral hernia
5. Age >18 years
6. Consent to the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
350

Key exclusion criteria
1. Female gender
2. Change of diagnosis during operation (e.g. femoral hernia)
3. Change of operative procedure during operation (e.g. TAPP)

Date of first enrolment
01/01/2004

Date of final enrolment
01/06/2006

Locations

Countries of recruitment

Switzerland

Study participating centre
Schoenenwerdstrasse 1
Schlieren
Switzerland
8952

Sponsor information

Organisation
Spital Limmattal, Department of Surgery (Switzerland)

Sponsor details
Urdorferstrasse 100
Schlieren
Switzerland
8952

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0591e2567

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Surgery, Spital Limmattal (Switzerland)

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