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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

Registration date
24/11/2005

Last Edited
14/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Inguinal pain and discomfort at 6 weeks and 2 years.

Key secondary outcome(s))
1. Hernia recurrence
2. Complications
3. Quality of life

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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)

ROR
https://ror.org/0591e2567

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Surgery, Spital Limmattal (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration