The Impact of Fibrin fixation of macroporous mesheS in TransAbdominal PrePeritoneal hernia repair

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------------------|---|--|--|--|
| 21/03/2007 | | ☐ Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 13/08/2007 | Completed | [X] Results | | |
| Last Edited 12/04/2021 | Condition category Digestive System | [] Individual participant data | | |
| 12/04/2021 | Digestive System | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The Impact of Fibrin fixation of macroporous mesheS in TransAbdominal PrePeritoneal hernia repair

Acronym

FSTAPP

Study objectives

Reduction of postoperative pain and improved quality of life due to the use of atraumatic mesh fixation with a tissue sealant.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Granted by local ethics committee (Ethikkommission der Stadt Wien) on the 30th June 2006 (ref: EK 06-019-0306).

Study design

Prospective, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Primary unilateral- and bilateral inguinal hernia

Interventions

Transabdominal laparoscopic inguinal hernia repair in general anaesthesia. The operation is a standard procedure.

Intervention Type

Other

Phase

Primary outcome measure

Quality of Life assessed with the 36-item Short Form questionaire (SF-36) and pain assessed with the Visual Analoge Scale (VAS).

Secondary outcome measures

Recurrences, postoperative complications assessed by clinical examination and ultrasound.

Overall study start date

01/05/2006

Completion date

01/05/2009

Eligibility

Key inclusion criteria

- 1. Age between 18 and 70 years
- 2. Primary uni- and bilateral inguinal hernia

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

100

Total final enrolment

89

Key exclusion criteria

- 1. Unwilling to participate or no insight in purpose of the study
- 2. Not fluent in the German language
- 3. Pregnancy
- 4. Chronic condition/disease associated with permanent pain

Date of first enrolment

01/05/2006

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Austria

Study participating centre 2nd Department of Surgery

Vienna Austria 1200

Sponsor information

Organisation

Ludwig Boltzmann Institute for Traumatology (Austria)

Sponsor details

Donaueschingenstr. 13 Vienna Austria 1200 +43 (0)13 311 0464 office@lbitrauma.org

Sponsor type

Research organisation

Website

http://www.lbitrauma.org/

ROR

https://ror.org/00a8zdv13

Funder(s)

Funder type

Research organisation

Funder Name

Ludwig Boltzmann Institute for Traumatology, Cluster for Tissue Regeneration (Austria)

Results and Publications

Publication and dissemination planNot 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? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 01/01/2012 | 12/04/2021 | Yes | No |