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

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

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

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

Not Specified

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
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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 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?
Results article		01/01/2012	12/04/2021	Yes	No