

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

Submission date 21/03/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/04/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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
CT1

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

Recurrences, postoperative complications assessed by clinical examination and ultrasound.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

ROR

<https://ror.org/00a8zd13>

Funder(s)**Funder type**

Research organisation

Funder Name

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

Results and Publications**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