

# Trans rectus sheath preperitoneal mesh repair (TREPP) versus transinguinal preperitoneal procedure (TIPP) for inguinal hernia repair: a multi-center randomized controlled trial.

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Reduce postoperative chronic pain after open inguinal hernia repair.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40117

### Source

ToetsingOnline

### Brief title

The ENTREPPMENT trial: TREPP vs TIPP

### Condition

- Other condition
- Connective tissue disorders (excl congenital)
- Soft tissue therapeutic procedures

### Synonym

groin hernia, inguinal hernia

### Health condition

liesbreuk herstel

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** eigen financiële middelen van de deelnemende centra

## Intervention

**Keyword:** groin hernia, inguinal hernia, trans rectus sheath preperitoneal mesh repair (TREPP), transinguinal preperitoneal procedure (TIPP)

## Outcome measures

### Primary outcome

Postoperative chronic pain

### Secondary outcome

Health status; recurrence; cost analysis; serious adverse events

## Study description

### Background summary

Optimal open preperitoneal inguinal hernia repair.

The current main problem after Lichtenstein (gold standard) is postoperative chronic pain.

TIPP has proven (in the TULIP trial) to reduce postoperative chronic pain compared to Lichtenstein, therefore we use TIPP as control intervention in this trial.

A new technique has been developed: transrectus sheath preperitoneal mesh repair (TREPP), in which via open approach a polysoft mesh is positioned in the preperitoneal space. Results of the first 1000 patients show a low recurrence rate, comparable to Lichtenstein; and few patients with postoperative chronic pain.

This trial will compare TREPP with TIPP, in a randomized trial.

## Study objective

Reduce postoperative chronic pain after open inguinal hernia repair.

## Study design

RCT, multi center.

Randomisation: TREPP of TIPP.

Questionnaires with every follow up at outpatient department.

## Intervention

TREPP or TIPP; both open preperitoneal mesh repair for inguinal hernia.

TIPP: via inguinal canal mesh positioning in the preperitoneal space

TREPP: via anterior rectus sheath mesh positioning in the preperitoneal space.

## Study burden and risks

No other risk than normal operation risk.

Burden consists of 2 extra outpatient clinic visits.

## Contacts

### Public

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### Scientific

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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

\*primary, groin hernia, unilateral

\*age >18 years and < 80 years

\*ASA classification 1-3

\*signed informed consent

### Exclusion criteria

\*recurrences

\*scrotal hernia

\*femoral hernia

\*bilateral hernia

\*ASA >3

\*incarcerated hernia

\*psychiatric disease

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-02-2014
Enrollment:	800
Type:	Actual

## Ethics review

Approved WMO	
Date:	24-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	20-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
Other	ISRTCN18591339
CCMO	NL38842.091.12