

# The Total Extra Peritoneal (TEP) method versus the Transinguinal Preperitoneal Technique (TIPP) for inguinal hernia repair.

<b>Submission date</b> 31/01/2010	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/02/2010	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/02/2012	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Giel G Koning

### Contact details

Department of Surgery,  
Radboud University Medical Centre  
Geert Grooteplein-Zuid 10  
Nijmegen  
Netherlands  
6525 GA

## Additional identifiers

### Protocol serial number

NL31388.091.10

## Study information

### Scientific Title

The Total Extra Peritoneal (TEP) method versus the Transinguinal Preperitoneal Technique (TIPP) for inguinal hernia repair: A multicentre randomised controlled trial.

**Acronym**

GLADIOLA

**Study objectives**

TIPP has less adverse events than TEP.

**Further reading:**

The Tilburg double blind randomised controlled trial comparing inguinal hernia repair according to Lichtenstein and the transinguinal preperitoneal technique.

Trials. 2009 Sep 25;10:89.

<http://www.ncbi.nlm.nih.gov/pubmed/19781069>

<http://www.controlled-trials.com/isrctn93798494>

More information on hernia, treatment and research can be found at [http:// www.liesbreukcentrumbrabant.nl](http://www.liesbreukcentrumbrabant.nl)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

METC judgement: waiting for approval

**Study design**

Multicentre randomised active controlled parallel group trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Inguinal hernia

**Interventions**

As of 04/01/2012 the status of this record was changed to 'stopped' as the trial never started.

900 patients will be randomly allocated to anterior

inguinal hernia repair according to the transinguinal preperitoneal technique (TIPP) or totally extra peritoneal (TEP) technique, both with soft mesh.

The total duration of follow-up will be one year, post-operatively.

**Intervention Type**

Procedure/Surgery

**Phase**

Not Specified

**Primary outcome(s)**

1. Incidence of adverse events
2. Chronic pain (Visual Analogue Score [VAS])

Data will be collected by VAS-diary and SF36-list (Health Status / Quality of Life). Digital forms will be filled in by the patients at the outpatient departments at 14 days, 3 months and one year after surgery.

### **Key secondary outcome(s)**

1. Costs
2. Quality of life (SF-36)
3. Return to daily activities
4. Return to work

Data will be collected by VAS-diary and SF36-list (Health Status / Quality of Life). Digital forms will be filled in by the patients at the outpatient departments at 14 days, 3 months and one year after surgery.

### **Completion date**

12/12/2012

## **Eligibility**

### **Key inclusion criteria**

1. Primary groin hernia, unilateral
2. Age > 18, < 80 years
3. American Society of Anaesthesiologists (ASA) classification 1-3
4. Signed informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Recurrences
2. Age <18 or >80 years
3. Scrotal hernia
4. ASA classification >4
5. Acute incarcerated inguinal hernia

6. Psychiatric disease or other factors which make follow up or questionnaires unreliable
7. Previous preperitoneal surgery (e.g. radical prostatectomy)
8. Joint sessions (urology, vasectomy etc.)

**Date of first enrolment**

01/03/2010

**Date of final enrolment**

12/12/2012

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Department of Surgery,

Nijmegen

Netherlands

6525 GA

## Sponsor information

**Organisation**

Radboud University Medical Centre, Nijmegen (Netherlands)

**ROR**

<https://ror.org/05wg1m734>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Radboud University Medical Centre, Nijmegen (Netherlands)

## 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes