

# 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

## Study website

<http://www.gladiola.nl>

## 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

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Patient information material may be found at <http://www.gladiola.nl>

## 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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

01/03/2010

## **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

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

900

**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)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.umcn.nl/Zorg/Afdelingen/Heelkunde>

**ROR**

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

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Radboud University Medical Centre, Nijmegen (Netherlands)

## **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