

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

Submission date 31/01/2010	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/02/2010	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/02/2012	Condition category 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes