ISRCTN26433218 https://doi.org/10.1186/ISRCTN26433218

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

Submission date 31/01/2010	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/02/2010	**Overall study status** Stopped	
Last Edited 13/02/2012	**Condition category** Surgery	

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

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