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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
Registration date 22/02/2010	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 13/02/2012	**Condition category** Surgery	[_] Individual participant data [_] 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

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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

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