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Pain after kugel versus lichtenstein repair: a randomised trial

Submission date	Recruitment status	[_] Prospectively registered
28/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/01/2021	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S Nienhuijs

Contact details
Canisius-Wilhelmina Hospital
P.O. Box 9015
Nijmegen
Netherlands
6500 GS
+31 (0)24 365 7657
s.nienhuijs@hccnet.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL779, NTR790

Study information

Scientific Title
Pain after kugel versus lichtenstein repair: a randomised trial

Study objectives
The open pre-peritoneal approach in inguinal hernia repair might have the benefit of a mesh in the preferred space without the disadvantages of an endoscopic procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received by the local ethics board (CMO Regio Arnhem-Nijmegen), on the 22-12-2003 (ref: JvG/CMO 0301).

Study design
Randomised, controlled, parallel group, single blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pain, Inguinal hernia

Interventions
The Lichtenstein procedure and the Kugel procedure for inguinal hernias.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Visual Analogue Sccale (VAS) pain score at three months postoperatively.

Secondary outcome measures

1. VAS pain scores and consumed analgesics during the first two weeks postoperatively
2. Pain Disability Index scores
3. Neurological disturbances

Overall study start date
01/12/2004

Completion date
01/10/2005

Eligibility

Key inclusion criteria
Adult patients who had been referred for elective primary, unilateral inguinal hernia repair and gave informed consent.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
172

Total final enrolment
172

Key exclusion criteria
An irreducible inguinoscrotal hernia or previous procedures using the preperitoneal approach

Date of first enrolment
01/12/2004

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
Netherlands

Study participating centre

Canisius-Wilhelmina Hospital
Nijmegen
Netherlands
6500 GS

Sponsor information

Organisation
Canisius Wilhelmina Hospital (The Netherlands)

Sponsor details
Postbus 9015
Nijmegen
Netherlands
6500 GS

Sponsor type
Hospital/treatment centre

Website
http://www.cwz.nl/

ROR
https://ror.org/027vts844

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Canisius-Wilhelmina Hospital (The 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2007	14/01/2021	Yes	No