Pain after kugel versus lichtenstein repair: a randomised trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/12/2006		☐ Protocol		
Registration date 28/12/2006	Overall study status Completed	Statistical analysis plan		
		[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

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Contact details

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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 summaryNot 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