

Pain after kugel versus lichtenstein repair: a randomised trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Visual Analogue Sscale (VAS) pain score at three months postoperatively.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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)

ROR

<https://ror.org/027vts844>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Canisius-Wilhelmina Hospital (The 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?
Results article	results	01/09/2007	14/01/2021	Yes	No