Pain after Kugel versus Lichtenstein repair: a randomized trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22718

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

VAS pain score at three months postoperatively.

Secondary outcome

VAS pain scores and consumed analgesics during the first two weeks postoperatively, Pain Disability Index scores, neuroligical disturbances.

Study description

Background summary

The open preperitoneal approach in inguinal hernia repair, like the Kugel procedure, might have the benefit of a mesh in the preferred space without the disadvantages of an endoscopic procedure. Therefore, a total of 172 patients with primary inguinal hernia was randomised to undergo either the standard procedure of Lichtenstein or Kugel hernioplasty. Primary endpoint was pain three months postoperatively, as persistent chronic pain is the most prominent complication of inguinal hernia repair. Other collected data included visual analogue scale pain scores and consumed analgesics during the first two weeks postoperatively, identification nerves in the operative field, neurological examination at three months, pain description by the patient and Pain Disability Index score.

Study objective

The open preperitoneal approach in inguinal hernia repair might have the benefit of a mesh in the preferred space without the disadvantages of an endoscopic procedure.

Study design

N/A

Intervention

The Lichtenstein procedure and the Kugel procedure for inguinal hernias.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

An irreducible inguinoscrotal hernia or previous procedures using the preperitoneal approach.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2004
Enrollment:	172
Type:	Actual

Ethics review

Positive opinion

Date:	04-10-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL779
NTR-old	NTR790
Other	: N/A
ISRCTN	ISRCTN47267588

Study results

Summary results
World J Surg. 2007 Sep;31(9):1751-7; discussion 1758-9. Epub 2007 May 18.