

Inguinal hernia management: operation or observation? A randomised controlled multicenter trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26819

Source

NTR

Brief title

N/A

Health condition

inguinal hernia;liesbreuk

Sponsors and support

Source(s) of monetary or material Support: ZonMw Programma Doelmatigheid
Erasmus MC Interne Doelmatigheid

Intervention

Outcome measures

Primary outcome

The mean of 4 pain/discomfort scores during a follow-up period of 3 years.

Secondary outcome

Quality Adjusted Life Years (QALY) with quality weights measured with the EuroQol and in a sensitivity analysis with a transformed SF-36 utility weight, medical and non-medical costs and the event-free survival at 2 years.

Study description

Background summary

The presence of an inguinal hernia is an indication for an elective herniorrhaphy if no contraindications are present. However, life expectancy is equal for surgical and observational management. Additionally, recent studies indicate that there is a high incidence of chronic postoperative pain after inguinal hernia surgery.

The primary objective of this multicentre study is to investigate whether abstaining from operation is a better alternative to surgical treatment in male inguinal hernia patients.

- The target sample of 800 men will be randomly assigned to either surgical or observational non-surgical management.

The outcomes of the study are pain/discomfort, quality of life, event-free survival and costs.

To determine whether there is any difference in the mean of pain/discomfort scores (4 point scale, 0-3) during follow-up with 0,15 points and a power of 80%, the required sample size in each group is 400 patients. With the help of a Student's t-test a non-inferiority hypothesis will be tested. The hypothesis states that both groups have had the same mean pain/discomfort scores.

The secondary objective is to investigate whether a non-surgical approach is cost-effective compared to current practice (hernia operation).

The third objective is a comparison of the event-free survivorship functions of both groups.

The fourth objective is an evaluation of the baseline risk factors in the not-operated group with respect to their ability to predict which type of patients will require surgery during the follow-up period.

Study objective

Non-inferiority hypothesis: observation is not inferior to operation with respect to the mean of pain and discomfort during 3 years follow-up.

Intervention

1. Operation;
2. No intervention, observational management of the inguinal hernia.

Contacts

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Eligibility criteria

Inclusion criteria

1. Unilateral inguinal hernia;
2. Males;
3. Medial or lateral inguinal hernia;
4. Age \geq 50 years;
5. Description I or II of pain or discomfort interfering with daily activity;
6. Primary or recurrent inguinal hernia;
7. Informed consent (addendum V).

Exclusion criteria

1. Gender: female;

2. Bilateral inguinal hernia;
3. Femoral hernia;
4. Description III or IV of pain or discomfort interfering with daily activity;
5. Acute hernia complication (bowel obstruction, incarceration, strangulation, peritonitis or perforation);
6. Patient classified as American Society of Anaesthesiologist Class 4;
7. Scrotal hernia (cannot be corrected laparoscopically);
8. Patient is unable to speak Dutch;
9. Physical activity: patient travels regularly during which professional medical help is not always accessible;
10. Inguinal hernia not apparent during ultrasonography.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date: 05-09-2005

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	NL184
NTR-old	NTR221
Other	: N/A
ISRCTN	ISRCTN31866667

Study results

Summary results

N/A