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
Nationaal Trial Register

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 herniorraphy if no contra-indications 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

Public
Erasmus Medical Center, Department of General Surgery,
Molewaterplein 40/50
J. Jeekel
Molewaterplein 40/50
Rotterdam 3015 GD
The Netherlands
+31 (0)10 4633718
Scientific
Erasmus Medical Center, Department of General Surgery,
Molewaterplein 40/50
J. Jeekel
Molewaterplein 40/50
Rotterdam 3015 GD
The Netherlands
+31 (0)10 4633718

Eligibility criteria

Inclusion criteria

1. Unilateral inguinal hernia;

2. Males;

3. Medial or lateral inguinal hernia;

4. Age ¡Ý 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