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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26819

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

inguinal hernia;liesbreuk

Ondersteuning

Overige ondersteuning: ZonMw Programma Doelmatigheid
Erasmus MC Interne Doelmatigheid

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

1. Operation;

2. No intervention, observational management of the inguinal hernia.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL184
NTR-old	NTR221
Ander register	: N/A
ISRCTN	ISRCTN31866667

Resultaten

Samenvatting resultaten
N/A