

# 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.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON26819

### Bron

NTR

### 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 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.

## 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

## Publiek

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## Wetenschappelijk

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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  $\geq$  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).

### 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
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

### 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