INguinal hernia: operative or Conservative Approach (INCA TRIAL)?

Gepubliceerd: 15-03-2006 Laatst bijgewerkt: 18-08-2022

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-OMON24130

Bron
Nationaal Trial Register

Verkorte titel
INCA trial

Ondersteuning

Overige ondersteuning: ZonMw
Interne Doelmatigheid ErasmusMC

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Operative correction of the inguinal hernia or observative management.

Contactpersonen

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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 >= 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 or Class 5;

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-03-2006
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	NL573
NTR-old	NTR629
Ander register	: N/A
ISRCTN	ISRCTN31866667

Resultaten

Samenvatting resultaten
N/A