INCH-Trial.

Gepubliceerd: 14-03-2011 Laatst bijgewerkt: 18-08-2022

Our hypothesis is that laparoscopic incisional hernia repair comes with a significant shorter hospital stay compared to open incisional hernia repair.

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

Samenvatting

ID

NL-OMON25958

Bron
NTR

Verkorte titel
INCH-Trial

Aandoening

Incisional hernia.

Ondersteuning

Primaire sponsor: Foreest Instituut Alkmaar: sponsoring obtained
ZonMW: in progress
Overige ondersteuning: Foreest Instituut Alkmaar

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint is length of hospital stay after an incisional hernia repair.

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE:

Annually approximately 100.000 patients undergo a laparotomy in the Netherlands. About 15,000 of these
patients will develop an incisional hernia. Both open and laparoscopic surgical repair have been proven to be safe. However, the most effective treatment of incisional hernias remains unclear. This study, the 'INCH-trial', comparing cost-effectiveness of open and laparoscopic incisional hernia repair, is therefore needed.

STUDY DESIGN:

A randomized multi-center clinical trial comparing cost-effectiveness of open and laparoscopic repair of incisional hernias.

STUDY POPULATION:

Patients with a symptomatic incisional hernia, eligible for laparoscopic and open incisional hernia repair.

INTERVENTION:

Only surgeons, experienced in both open and laparoscopic incisional hernia repair, will participate in the INCH trial. Patients are randomized for either open or laparoscopic incisional hernia repair. In both surgical techniques, a mesh is placed under or on top of the fascia, with a minimal overlap of 5 cm.

OUTCOME MEASURES:

Primary endpoint is length of hospital stay after an incisional hernia repair. Secondary endpoints are
time to full recovery within three months after index surgery, post-operative complications, costs, recurrences, mortality andquality of life.

SAMPLE SIZE CALCULATION/ DATA ANALYSIS:

Our hypothesis is that laparoscopic incisional hernia repair comes with a significant shorter hospital stay compared to open incisional hernia repair. A difference of 2< days is considered significant. One-hunderd-and-thirty-five patients are needed in each treatment arm.

ECONOMIC EVALUATION:

The economic evaluation will be performed from a societal perspective. Primary outcomes are costs per patient related to time-to-recovery and quality of life.

TIME SCHEDULE:

Two-hundred-seventy patients are needed (135 per arm). A follow-up period of 3 months is needed to meet the primary end-point. Follow-up will continue to meet the secondary end-points.

Doel van het onderzoek

Our hypothesis is that laparoscopic incisional hernia repair comes with a significant shorter hospital stay compared to open incisional hernia repair.

Onderzoeksopzet

28 months are needed for accrual of a total of 270 patients (135 per arm). This is followed by 3 months follow-up period to meet the primary end-point. To meet the secondary end-points the follow-up is continued at 1, 3 and five years after index surgery.

Onderzoeksproduct en/of interventie

Only surgeons, experienced in both open and laparoscopic incisional hernia repair, will participate in the INCH-trial. Patients are randomized for either open or laparoscopic incisional hernia repair. In both surgical techniques, a mesh is placed under or on top of the fascia, with a minimal overlap of 5 cm.

Contactpersonen

Publiek

de Boelenlaan 1117
M.M. Poelman
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4444444

Wetenschappelijk

de Boelenlaan 1117
M.M. Poelman
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4444444

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients, who are referred to the surgical clinic for assessment of an incisional hernia, either primary or recurrent. Imaging of the abdomen will only be done when it is unclear whether an incisional hernia is present. The need for surgery will be determined; pain, severe discomfort and episodes of visceral incarceration are indications for surgery. Only symptomatic patients will get a surgical correction of the incisional hernia. After consenting to the study, the patient will be randomized to either open or laparoscopic repair.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Age under 18;

3. Abdominalostomy;

4. History of open abdomen treatment;

5. Mentally or cognitively unable to be consented;

6. A life expectancy of less than one year;

7. Immune-compromised patients;

8. ASA>3 (ASA: scoring system of the American Society of Anaesthesiologists).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2011
Aantal proefpersonen:	270
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-03-2011
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	NL2679
NTR-old	NTR2808
Ander register	ZonMw : 80-82310-97-12117
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A