# INCH-Trial.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25958

**Source**
NTR

**Brief title**
INCH-Trial

**Health condition**

Incisional hernia.

### Sponsors and support

**Primary sponsor:** Foreest Instituut Alkmaar: sponsoring obtained
ZonMW: in progress
**Source(s) of monetary or material Support:** Foreest Instituut Alkmaar

### Intervention

### Outcome measures

#### Primary outcome

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

#### Secondary outcome

Secondary endpoints are time to full recovery within three months after index surgery, post-operative complications, costs, recurrences, mortality and quality of life.

# Study description

**Background summary**

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.

### Study objective

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

### Study design

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.

### 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.

## Contacts

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# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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).

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2011 |
| Enrollment: | 270 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 14-03-2011 |
| 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 | NL2679 |
| NTR-old | NTR2808 |
| Other | ZonMw : 80-82310-97-12117 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A