INCH-trial: A multicenter randomized controlled trial comparing the efficacy of conventional open surgery and laparoscopic surgery for incisional-hernia repair.

Published: 11-08-2011
Last updated: 16-11-2024

The main goal of the trial is to establish whether laparoscopic incisional hernia repair is superior to conventional open incisional hernia repair in terms of cost-effectiveness. This is measured through length of hospital stay and quality of life....

Ethical review	Approved WMO
Status	Completed
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON41404

Source
ToetsingOnline

Brief title
INCH-trial

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
ventral hernia/ incisional hernia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Door een subsidie van het Foreest instituut in Alkmaar (42000 euro toegekend). Aanvraag van een ZonMW doelmatigheid-subsidie (onderdeel effecten en kosten) loopt.

Intervention

Keyword: incisional hernia repair, laparoscopy versus open

Outcome measures

Primary outcome

Primary outcomes are:

-Length of hospital stay

-Quality of life measures through SF-36 and CCS.

Secondary outcome

Secondary endpoints are:

- Time to full recovery within a three months period.

-Re-operation rate for recurrence or complications of the incisional hernia

repair. The analysis will be continued after the cost-effectiveness study has

ended, a longer follow-up is needed to examine the recurrence-rate.

-28 days post surgery morbidity and mortality,

-Shape of the abdomen: a digital photograph of the abdomen using

raster-stereography will be taken pre- and post-operatively to analyse the

change in the abdominal shape.

-Total mean costs will be related to the following effect measures in the

cost-effectiveness analyses:

1) Time to full recovery

2) Quality-adjusted life-years (QALYs) based on the SF-36.

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 and quality 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. Because of an expected loss to follow-up, 300 patientes will be included.

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: For the INCH trial 2 months of study preparation are needed. Next, 28 months are needed for accrual of a total of 300 patients (150 per arm). This period is followed by 3 months of follow-up and 3 months of data

analysis and reporting.

Study objective

The main goal of the trial is to establish whether laparoscopic incisional hernia repair is superior to conventional open incisional hernia repair in terms of cost-effectiveness. This is measured through length of hospital stay and quality of life. Secondary endpoints are re-operation-rate (due to complications or recurrence), morbidity, mortality and shape of the abdomen.

Study design

Patients who fit the inclusion criteria and have an incisional hernia will be randomized using a computer generated randomization list which can be accessed electronically. Stratification will be by centre and by primary or recurrent incisional hernia. This trial is based on a superiority principle.

Intervention

Patients will either undergo laparoscopic or open incisional hernia repair. There two groups will be compared.

Study burden and risks

Apart for the normal surgical risks, no extra risks comes with consenting to this trial. The extra burdens are completing a diary for a few weeks, and some questionnaires when visiting the out-patient clinics.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who:
- have an incisional hernia
- the need/wish for surgical repair
- laparoscopic repair is feasible
gave informed consent

Exclusion criteria

Patients who:
- Are pregnant
- Have an ostomy
- Are younger than 18 years old
have an open abdomen treatment in the medical history.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-08-2012
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL34308.029.10