Suture Techniques to reduce the Incidence of The inCisional Hernia.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23451

Source
Nationaal Trial Register

Brief title
STITCH

Health condition

Abdominal surgery, midline incisions, suture technique, incisional hernia, burst abdomen, wound infection

Sponsors and support

Primary sponsor: Erasmus University Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmus MC internal cost efficacy grant (MRACE 2009)=intiator

Intervention

Outcome measures

Primary outcome

Incisional hernia occurence within one year clinically and/or radiographically detected.

Secondary outcome

1. Postoperative complications => burst abdomen and wound infection;

2. Pain;

3. Quality of life;

4. Cost effectiveness.

Study description

Background summary

Incisional hernia is the most common complication after abdominal surgery with a reported incidence of
up to 15% at 1 year follow-up. In The Netherlands, 100.000 laparotomies and 4000 incisional hernia
repairs are performed annually. The costs of hernia repair (4 kEuro) hence amount to over 16 million
euro. Moreover, many patients with incisional hernia are not re-operated due to anticipated recurrence
rates of 30-60%. The major factor for development of incisional hernia is the surgical wound failure due
to insufficient suture techniques. The latter complication, which occurs in 1-4% of abdominal surgery,
involves bursting of the abdominal wound and the muscle layers, which causes the intestines to
protrude from the incision. It is associated with a high incidence of surgical site infections, prolonged
hospital stay and high mortality rates.
Recent clinical and experimental data suggest that a relatively new technique with many small tissue
bites should be more effective in the prevention of incisional hernia when compared to the standard
large bite technique.

We propose a multicenter double blind RCT to compare the routinely used large bite technique with the
small bites technique.

Objective of the study:

Primary question:

1. Which bite size should be used to close a midline incision to prevent incisional hernia?

Secondary questions:

2. Is there a difference in postoperative complications between the two patient groups?

3. Is there a difference in postoperative pain between the two patient groups?

4. Is there a difference in postoperative quality of life between the two patient groups?

5. Is it cost-effective to use the small bites technique?

The trial will be a double blinded randomized controlled prospective trial, in which the large bites technique will be compared with the small bites technique. Patients will be preoperatively randomized in two groups to either receive closure with the large tissue bites technique or with the small tissue bites technique. Patients will be kept unaware of the procedure until the endpoint of the trial. Surgeons or surgical residents and radiologists blinded for the procedure will do outpatient clinic controls.

Study population:

550 surgical patients who will undergo a midline laparotomy will be asked to join this study.

Study objective

Recent clinical and experimental data suggest that a relatively new technique with many small tissue bites should be more effective in the prevention of incisional hernia when compared to the standard large bite technique.

We propose a multicenter double blind RCT to compare the routinely used large bite technique with the small bites technique.

Study design

At 1 and 12 months, a clinical examination and ultrasound examination will be performed by an examiner blinded to the procedure to examine the midline for any (a-)symptomatic incisional hernias.

Participating patients will be asked to fill in booklets containing quality of life questionnaires before surgery and at 1, 3, 6 and 12 months after surgery.

Intervention

In one group of 275 patients the conventional large bites technique will be applied with bites widths of
1,5 cm and inter suture spacing of 1 cm with the use of slowly absorbable 1-0 double loop suture
material with a 48 mm needle.

In the other group of 275 patients the small bites technique will be applied with bite widths of 0,5 cm
and inter suture spacing of 0,5 cm with the use of slowly absorbable 2-0 single suture material with a
36 mm needle only in the linea alba. In the small bites technique there will be twice as many stitches
with a smaller needle and thinner suture material.

Contacts

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Eligibility criteria

Inclusion criteria

1. Signed informed consent;

2. Midline incision;

3. Age >= 18 years.

Exclusion criteria

1. Previous midline incision within 3 months before surgery;

2. Previous incisional hernia or burst;

3. Abdoman after a midline incision;

4. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2009
Enrollment:	550
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-10-2009
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	NL1935
NTR-old	NTR2052
Other	MEC/NL : 2009-026/26225.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A