Suture Techniques to reduce the Incidence of The inCisional Hernia

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Primary question• Which bite size should be used to close a midline incision to prevent incisional hernia?Secondary questions• Is there a difference in postoperative complications between the two patient groups?• Is there a difference in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37004

Source
ToetsingOnline

Brief title
STITCH trial

Condition

- Other condition
- Soft tissue therapeutic procedures

Synonym
burst abdomen, incisional hernia

Health condition

preventie van chirurgische complicaties

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Ethicon hechtdraden fabrikant (Johnson en Johnson),Johnson & Johnson

Intervention

Keyword: Abdominal surgery, Incisional hernia, suture technique

Outcome measures

Primary outcome

Incisional hernia occurrence within one year

Secondary outcome

Postoperative complications, like burst abdomen

Pain

Quality of life

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.

Study objective

Primary question
• Which bite size should be used to close a midline incision to prevent incisional hernia?
Secondary questions
• Is there a difference in postoperative complications between the two patient groups?
• Is there a difference in postoperative pain between the two patient groups?
• Is there a difference in postoperative quality of life between the two patient groups?
• Is it cost-effective to use the small bites technique?

Study design

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.

Intervention

In one group of 288 patients the conventional large bites technique will be applied with bites widths of 1 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 288 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 31 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. In the Swedish hospitals where the small bites techniques has been used for many years, this combination proved the easiest and safest method to handle the small bites technique.

Suture length wound length ratios of 4:1 are aimed at and will be calculated by the nurse after closure of the abdominal wall. In case of a lower ratio that 4:1 the surgeon will be advised to consider closing the fasia again. The number of stitched will be count by the nurse to control the bite size.

Study burden and risks

Both techniques are already applied in the clinic, so we expect a very small change of an increased complication rate. In case of a lower ratio that 4:1 the surgeon will be advised to consider closing the fasia again. The questionnaires will probably not be a big burden. The outpatient clinic visit after 30 days and 1 year can be combined with a regular outpatient visit. The abdominal wall ultrasounds will take some extra time and a few extra burdens.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Signed informed consent

All laparotomies with a midline incision
Age >= 18 years

Exclusion criteria

Previous incisional hernia after a midline incision
Previous midline incision within 3 months before surgery
Pregnant women

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2009
Enrollment:	576
Type:	Actual

Ethics review

Approved WMO

Date:	19-03-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	21-10-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-08-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-10-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26225.078.09