

# Suture Techniques to reduce the Incidence of The inCisional Hernia.

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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...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON23451

### Bron

Nationaal Trial Register

### Verkorte titel

STITCH

### Aandoening

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

### Ondersteuning

**Primaire sponsor:** Erasmus University Medical Center Rotterdam

**Overige ondersteuning:** Erasmus MC internal cost efficacy grant (MRACE 2009)=initiator

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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

# Toelichting onderzoek

## Achtergrond van het onderzoek

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.

### **Doel van het onderzoek**

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.

### **Onderzoeksopzet**

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.

### **Onderzoeksproduct en/of interventie**

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.

## Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Signed informed consent;
2. Midline incision;
3. Age  $\geq$  18 years.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous midline incision within 3 months before surgery;
2. Previous incisional hernia or burst;
3. Abdoman after a midline incision;
4. Pregnancy.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Geneesmiddel

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2009
Aantal proefpersonen:	550
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	12-10-2009
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	NL1935
NTR-old	NTR2052
Ander register	MEC/NL : 2009-026/26225.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Resultaten

### Samenvatting resultaten

N/A