# Primary Mesh Closure of Abdominal Midline Wounds
# A double blind Randomized Controlled Trial

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The objective of this study is to evaluate the usefulness of closing the abdomen with a prosthetic mesh after laparotomy for aortic aneurysm repair or in patients with a BMI larger than 27 in order to prevent an incisional hernia. The aim is to...

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

## Summary

### ID

NL-OMON39427

**Source**
ToetsingOnline

**Brief title**
PRIMA trial

### Condition

- Other condition

**Synonym**
incisional hernia

**Health condition**

ventrale hernias na laparotomie (chirurgische complicatie)

**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

## Intervention

**Keyword:** - incision, - incisional hernia, - prevention, - surgical mesh

## Outcome measures

### Primary outcome

Primary outcome

· Incisional hernia occurrence

### Secondary outcome

Secondary outcome

· Postoperative complications

· Pain

· Quality of life

· Cost effectiveness

# Study description

### Background summary

Incisional hernia is the most common longterm complication in abdominal surgery. In about 10 to 20 % of all patients receiving abdominal surgery, an incisional hernia will develop. In teh Netherlands this leads to about 5000 incisional hernia corrections each year.
Some high risk groups have a very incidence of incisional hernia: aortic aneurysm patients and patients having an BMI larger than 27. About 30 % of these patients will develop an incisional hernia.
Up to this dat only small studies have been performed to investigate the effectiveness of preventive mesh placement. The results are hopefull, but a

randomised controlled trial had not yet been performed.

### Study objective

The objective of this study is to evaluate the usefulness of closing the abdomen with a prosthetic mesh after laparotomy for aortic aneurysm repair or in patients with a BMI larger than 27 in order to prevent an incisional hernia. The aim is to reduce the risk of incisional hernia after laparotomy in the study group from 30 % to 10 %.

### Study design

This is a double blinded randomized controlled trial. Before surgery, patients will be randomized either to receive primary closure with a suture or primary closure with a prosthetic mesh.
A total 480 patients will be randomized into 3 groupes.

### Intervention

During the closure of the abdomen a mesh will be placed on or in the abdominal wall.

### Study burden and risks

The intervention will take place during surgery and will delay the surgery approximately 15 minutes. The risks consit of wound complications related to mesh placement. Surgical site infection and seroma formation are the most important complications. However, these are mild and respond well to therapy. The benefit of mesh placement is the reduction of the incidence of incisional hernia formation from 30 to 10 %.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Every elective midline laparotomy for patients with Abdominal Aortic Aneurysm and patients with a BMI of more than 27.

## Exclusion criteria

· Age < 18 years
· Emergency procedure
· Inclusion in other trials
· Aortic reconstruction for obstructive disease

# Study design

## Design

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

**Primary purpose:** Prevention

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-02-2009 |
| Enrollment: | 280 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 01-10-2007 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 15-12-2009 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 13-09-2010 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 15-02-2011 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 14-11-2011 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 28-05-2013 |

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| 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 | NL18461.078.07 |