# Long-term incidence of incisional hernia after abdominal surgery

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### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr AGM Hoofwijk

### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

### Scientific Title

Long-term incidence of incisional hernia after abdominal surgery: a prospective randomised trial comparing two suture materials

### Acronym

Buiksluittrial (Belly Close Trial)

### **Study objectives**

Non-absorbable sutures (Prolene®) cause less incisional hernias than slow-absorbing suture materials (PDS®) while not causing more other complications such as suture sinus or wound infection.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Local Medical Ethics Committee (Medisch Ethische Toetsingscommissie) approved in 2001 (ref: 01.005)

### Study design

Prospective randomised clinical trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Abdominal wall: incisional hernia

#### **Interventions**

Closure of the abdominal fascia with non absorbable (Prolene®) or slow-absorbable (PDS®) suture-materials. All patients were followed up by outpatient visits after 1 month and 6 month intervals during which they were interviewed, examined and during which ultrasonography of the abdominal wall was performed.

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

Incidence of incisional hernia, measured until 6 months (end of follow-up)

### Secondary outcome measures

Measured until 6 months (end of follow-up):

- 1. Wound infection
- 2. Suture sinus

### Overall study start date

01/10/2001

### Completion date

01/01/2005

# **Eligibility**

# Key inclusion criteria

- 1. Aged 18 86 years, either sex
- 2. Undergoing an elective or emergency median laparotomy at the General Surgery Department of the Orbis Medical Centre in the Netherlands

### Participant type(s)

**Patient** 

### Age group

Adult

### Lower age limit

18 Years

#### Sex

Both

### Target number of participants

600

### Total final enrolment

223

### Key exclusion criteria

- 1. Pregnancy
- 2. Presence of an abdominal hernia
- 3. No informed consent
- 4. Aged younger than 18 years
- 5. Life expectancy of less than 1 year

### Date of first enrolment

# Date of final enrolment 01/01/2005

# Locations

**Countries of recruitment**Netherlands

Study participating centre
Dr. H. van der Hoffplein 1
Sittard-Geleen
Netherlands
6130 MB

# Sponsor information

### Organisation

Orbis Medical Centre (Netherlands)

### Sponsor details

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### Sponsor type

Hospital/treatment centre

### Website

http://www.orbisconcern.nl/

# Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Orbis Medical Centre (Netherlands)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2011	18/12/2020	Yes	No