

Long-term incidence of incisional hernia after abdominal surgery

Submission date 13/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/12/2020	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

1. Wound infection
2. Suture sinus

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

01/10/2001

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)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Orbis Medical Centre (Netherlands)

Results and Publications

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