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Long-term incidence of incisional hernia after abdominal surgery

Submission date	Recruitment status	[_] Prospectively registered
13/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2020	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr AGM Hoofwijk

Contact details
Dr. H. van der Hoffplein 1
Sittard-Geleen
Netherlands
6130 MB
-
t.hoofwijk@orbisconcern.nl

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

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)

Sponsor details
c/o Dr AGM Hoofwijk
Department of General Surgery
PO Box 5500
Sittard
Netherlands
6130 MB
+31 (0)88 459 77 77
t.hoofwijk@orbisconcern.nl

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