A multicentre Prospective study in pAtients undergoing ventral herNia repair by open approach with intrA-peritoneal positioning using parietex* Composite vEntral pAtch.

Published: 15-07-2013
Last updated: 24-04-2024

Assessing the safety and efficacy of a new mesh (Parietex Composite Ventral Patch)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40149

Source
ToetsingOnline

Brief title
PANACEA-trial

Condition

- Soft tissue therapeutic procedures

Synonym
hernia / abdominal wall defect

Research involving
Human

Sponsors and support

Primary sponsor: Covidien

Source(s) of monetary or material Support: Covidien

Intervention

Keyword: epigastric hernia, hernia repair, mesh, umbilical hernia

Outcome measures

Primary outcome

Recurrene rate at 24 months based on physical and ultrasound examination.

Secondary outcome

Recurrence rate at 1,6 and 12 months / pain with NRS, consumption of analgesics

/ ease of mesh, operative details.

Study description

Background summary

Analogue to other hernia repairs, more ventral hernia repairs are mesh-based. It remains unclear which mesh to prefer.

Study objective

Assessing the safety and efficacy of a new mesh (Parietex Composite Ventral Patch)

Study design

Multicentre cohort study

Intervention

Open mesh-based ventral hernia repair

Study burden and risks

Burden (3 extra visits, an abdominal wall ultrasound at 2 years and a urinary test for females before inclusion) could be regarded as limited. Risks is the same as treatment without this trial.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

primary ventral hernia
maximum hernia size 4 cm
adults

Exclusion criteria

emergency procedure
pregnancy known/suspected/planned during study follow-up period

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-08-2013
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Mesh / Parietex Composite Ventral Patch
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-07-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	20-02-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	clinicaltrials.gov
CCMO	NL43841.060.13

Study results

Date completed: 12-07-2016

Actual enrolment: 8

Summary results
Trial is onging in other countries