Reinforcement of closure of stoma site

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To assess whether a biological mesh (collagen tissue matrix) reduces the incidence of clinically detectable stoma closure site hernias at two years compared to standard closure techniques.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Interventional

Summary

ID

NL-OMON40463

Source
ToetsingOnline

Brief title
Rocss-trial

Condition

- Abdominal hernias and other abdominal wall conditions
- Gastrointestinal therapeutic procedures

Synonym
abdominal hernia, incisional hernia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: firma LifeCell,LifeCell

Intervention

Keyword: Biological mesh, Reinforcement, Stoma, Wound healing

Outcome measures

Primary outcome

Occurrence of clinically detectable hernias at two years post closure

Secondary outcome

1. Radiological hernia rate at one year post closure. An exploratory analysis

will compare radiological hernia rate at 1 year with clinical hernia rate at

2 years to assess the value of using a CT scan as an early diagnostic tool of

incisional hernias.

2. Surgical re-intervention rate.

3. Surgical complications at 30 days and 1 year.

4. Quality of life and post-operative pain.

5. Cost-benefit analysis.

Study description

Background summary

Closure of complex and contaminated abdominal wounds is challenging and carries risks, including wound dehiscence and incisional hernias. Use of biological meshes in these situations may provide a safe method of reducing these complications, especially long-term incisional hernias. ROCSS will use stoma site closure as a model for biological mesh placement during any difficult contaminated abdominal wall closures.

Hernia at the site of stoma closure occurs in up to 30% of patients and is associated with adverse effects on quality of life. In up to 10% of cases, patients are submitted to complex re-operation which carries significant morbidity. Not all patients will report symptoms or undergo repair, as they do not wish to have a further major operation. Incisional hernias at the site of stomas closure form an important and well defined subgroup. If there is a measurable benefit from mesh insertion, elective use of a collagen mesh would warrant consideration in the closure of other difficult, contaminated abdominal wounds. This study will also provide useful information on the value of using a

CT scan as an early diagnostic tool of herniation, which could then be used in future abdominal wall studies as a surrogate endpoint for clinical hernia.

Study objective

To assess whether a biological mesh (collagen tissue matrix) reduces the incidence of clinically detectable stoma closure site hernias at two years compared to standard closure techniques.

Study design

The intervention in the experimental arm consists of suturing an acellular biological mesh derived from porcine dermis in the abdominal wall, followed by normal abdominal closure similar to the control arm. 560 patients will be randomised over 2 years from at least 30 centres. ROCSS will be a single blind randomised controlled trial with a CT scan at one year and clinical follow up at 2 years. Cost benefit analysis and quality of life analysis will be performed at 2 years.

Intervention

The intervention in the experimental arm consists of suturing an acellular biological mesh derived from porcine dermis in the abdominal wall defect, followed by closure of the skin, fascia and subcutis similar to the control arm.

Study burden and risks

Potential additional risk related to the use of biological mesh is increased postoperative pain and seroma formation, which is mostly transient and does not require invasive treatment. The extra burden of participation consists of additional radiation exposure, outpatient clinic visits and questionnaires.

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

Require an elective closure of an ileostomy or a colostomy. Those patients undergoing a Stoma closure involving both a colostomy and an ileostomy element are eligible and should be
Stratified as colostomy patients.
Be able and willing to provide written informed consent for the study
Be aged 18 years or over.

Exclusion criteria

Taking part in another clinical study which is related to the surgical procedure.
Allergic to any porcine or collagen products.
Unable or unwilling to provide written informed consent.

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2015
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Biological Mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47356.018.13