Clinical Evaluation of the Cohera Sylys* Surgical Sealant as an adjunct to standard bowel anastomosis closure

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Objectives: The purpose of this study is to establish the safety of the product.This study is designed to evaluate the safety of the device in protecting the anastomotic junction created during a stoma reversal procedure. The objectives of this...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON39012

Source
ToetsingOnline

Brief title
PRO-106-0028

Condition

- Gastrointestinal conditions NEC
- Obstetric and gynaecological therapeutic procedures

Synonym
Stoma reversal

Research involving
Human

Sponsors and support

Primary sponsor: Cohera Medical
Source(s) of monetary or material Support: Cohera Medical Inc.

Intervention

Keyword: bowel resiction, prevention anastomic leakage, Surgical sealant

Outcome measures

Primary outcome

Primary Endpoints

Safety data will be gathered with respect to the number, timing, severity, duration and resolution of device related adverse events occurring among study subjects.

Secondary outcome

Secondary Endpoints

* Length of hospital stay

* Reoperation rate

* Readmission rate

* Number/type of additional procedures due to complications

* Evaluation of the delivery method of the sealant

Number of adverse events associated with known complications of ileostomy reversal.

Known complications of ileostomy closure include:

* Anastomotic leak

* Wound infection

* Intra-abdominal abscess/sepsis

* Small bowel obstruction

* Incisional hernia

* Prolonged post-operative ileus

* Post-operative enterocutaneous fistula

Study description

Background summary

Protocol Title: Clinical Evaluation of the Cohera Sylys* Surgical Sealant as an adjunct to standard bowel anastomosis closure

Protocol Number: PRO-106-0028

Sponsor: Cohera Medical, Inc.
209 Sandusky St.
Pittsburgh, PA 15212
412-231-1500

Principal coordinating investigator: Prof. Dr. Bemelman

Location: 2 sites in The Netherlands

Device name: Sylys*

Additional background information is given in chapter 2 of the protocol.

Study objective

Objectives:
The purpose of this study is to establish the safety of the product.
This study is designed to evaluate the safety of the device in protecting the anastomotic junction created during a stoma reversal procedure.
The objectives of this clinical evaluation are:
* To determine the safety of the Sylys* device used during open ileostomy reversal procedures.
* Examine the performance of the delivery method.
The primary hypothesis for this study is that Sylys* Surgical Sealant is a safe adjunct to standard closure techniques during a stoma reversal procedure.
No claims regarding efficacy will be verified during this clinical investigation.
The study is a prospective, non-randomized, one treatment group, un-blinded study conducted on stoma reversal patients at 2 study centers. Subjects are enrolled in the trial for a period of 90 days.

Study design

Prospective Design
This clinical investigation is an open-label, prospective, unblinded multicenter study. The Patient Population to be studied will consist of a total of 15 test subjects. The data will be collected at 2 sites.

Intervention

Follow up:
Clinical assessments will be performed pre-operatively, intra-operatively, during hospital stay, at discharge from hospital, at 7 days (± 1 days), 30 days (± 3 days) and 90 days (± 3 days) post operatively.
The number of subjects required for this clinical investigation is fifteen.
The estimated time needed to enroll this number is 60 days. The expected duration of the clinical investigation is 5 months including 60 day enrollment and the 90 day follow up periods.

Study burden and risks

Risks to patients in this study include all those risks currently associated with ileostomy reversal procedures. These risks include, but are not limited to, the following; nausea, headache, back pain, surgical site infection and constipation.

If used as indicated, there are no known risks associated with the use of Sylys* as a surgical sealant. There may be potential risks of device failure if Sylys* is:
* Used in conjunction with other surgical adhesives or sealants, or other fluid preparations.
* Used in patients with known or suspected allergies to urethane-based or siloxane-based products.
It is possible that unanticipated risks may occur.

Contacts

Public
Cohera Medical

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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Be at least 18 years of age;
* Be in good general health in the opinion of the Investigator with no conditions that would significantly impact wound healing as determined by medical history and review of recent concomitant medications;
* Be scheduled for an ileostomy reversal procedure;
* Be willing to follow instructions for incision care;
* Agree to return for all follow-up evaluations specified in this protocol;
* Sign the informed consent.

Exclusion criteria

* Anesthesia Risk judged to be higher than ASA2
* Have severe co-morbid conditions that pose a high risk for surgery and adequate recovery (e.g., heart disease)
* Any condition involving compromised immune system
* Any condition known to effect wound healing, such as collagen vascular disease
* Known blood clotting disorder
* Be receiving antibiotic therapy for pre-existing condition or infection
* Concurrent use of fibrin sealants or other anastomosis care devices
* Be currently taking systemic steroids or immunosuppressive agents
* Have known or suspected allergy or sensitivity to any test materials or reagents
* Be participating in any current clinical trial or have participated in any clinical trial within 30 days of enrollment in this study

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):	16-04-2013
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Sylys Surgical Sealant
Registration:	No

Ethics review

Approved WMO Date:	20-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2013
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	NL43207.018.13