Non-randomised,open, multi-center trial evaluating feasibility and safety of Tachosil application on a colorectal anastomosis

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The primary efficacy variable is if the TachoSil application was feasible. A feasible application implies that the entire TachoSil adhere, TachoSil covers at least 1 cm beyond the margins of the anastomosis line and if more TachoSil sponges are used...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON31912

Source
ToetsingOnline

Brief title
Evaluation of Tachosil application on a colorectal anastomosis

Condition

- Anal and rectal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
leakage of colorectal anastomosis

Research involving
Human

Sponsors and support

Primary sponsor: Nycomed
Source(s) of monetary or material Support: nycomed bv

Intervention

Keyword: Application, Colorectal anastomosis, Tachosil, Trial

Outcome measures

Primary outcome

The primary efficacy endpoint is whether or not the TachoSil application was

feasible?

A feasible application implies that the entire Tachosil adheresl, TachoSil

covers at least 1 cm beyond the margins of the anastomosis line and if more

than one TachoSil sponge is used, they must overlab by at least 1 cm.

Secondary outcome

To establish and describe the optimal application method, the following

information will be collected:

· Use of suture or stapler for anastomosis formation

· Instruments used to facilitate the application

· Possibility of applying pressure on TachoSil sponge

· Number of TachoSil used

Study description

Background summary

The scope of this trial is to evaluate if it is possible to apply TachoSil

around rectal anastomosis and be able to use it in future clinical trials. Therefore the only focus is on the validation of the TachoSil application method and a control group is not feasible.

The adherence of the entire TachoSil and the location around the anastomotic line will be evaluated immediately following the application. The score will be assisted by video recording. To ensure an independent and uniform assessment, the recording will be assessed by an external, blinded assessor. In case of discrepancies, the assessment of the blinded assessor will be valid.

Furthermore, for educational purposes knowledge about the application will be gathered to describe the optimal process.

Study objective

The primary efficacy variable is if the TachoSil application was feasible.

A feasible application implies that the entire TachoSil adhere, TachoSil covers at least 1 cm beyond the margins of the anastomosis line and if more TachoSil sponges are used they must overlap by at least 1 cm.

Study design

Non-randomised, open, multi-center trial evaluating feasibility and safety of TachoSilÒ on a colorectal anastomosis.

Intervention

All patients will receive Tachosil

Study burden and risks

No additional risks are expected than those which could happen according the SPC of Tachosil

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

At screening
1. Has the patient given informed consent according to local requirements before any trial-related activities? A trial-related activity is any procedure that would not have been performed during the routine management of the subject
2. Is the subject 18 years of age or above?
3. Is the subject scheduled for elective resection of the rectum?
4. Is a colorectal anastomosis below the peritoneal reflexion planned?;For females of childbearing potential:
5. Does the patient use an acceptable contraceptive method (contraceptive pills, injection of prolonged gestagen, subdermal implantation, hormonal vaginal devices, transdermal patches or intrauterine device (IUD))?
6. Is the urine pregnancy test negative?

Exclusion criteria

Exclusion Criteria
At screening
1. Is the subject scheduled for emergency resection of the rectum?
2. Does the subject suffer from inflammatory bowel diseases?
3. Does the subject have a history of hyper sensitivity reactions after application of human fibrinogen, human thrombin and/or collagen of any origin?

4. Has the subject participated in any other trial with an investigational medical product (IMP) or device within 30 days before inclusion in this trial?
5. Does the subject participate or plan to participate in another clinical trial during the trial period?
For females of childbearing potential:
7. Is the subject pregnant or breast feeding?;Peroperative
7. Was an anastomosis different from the one defined in the inclusion criterias performed?
8. Did the subject receive any fibrin sealant glue, excluding TachoSil, during surgery?

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-07-2008
Enrollment:	7
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tachosil
Generic name:	Tachosil
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	03-04-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	17-03-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2007-007254-62-NL
CCMO	NL22494.041.08