Evaluation of TachoSil® Application on a Colorectal Anastomosis (TC-029-IM)

This study has been completed.

Sponsor:
Nycomed

Information provided by (Responsible Party):
Nycomed

ClinicalTrials.gov Identifier:
NCT00713661

First received: July 7, 2008
Last updated: May 4, 2012
Last verified: February 2012
History of Changes

Results First Received: December 20, 2011

Study Type:	Interventional
Study Design:	Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Colorectal Anastomosis
Intervention:	Drug: TachoSil®

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Subjects were divided into

- Surgery method: open or laparoscopic
- Location of the anastomosis:
  - anastomotic line in the low segment (approx. 0-5 cm from the anal verge)
  - anastomotic line in the mid or upper segment (approx. 5-12 cm from the anal verge)

Reporting Groups

	Description
Group 1: Open Surgery Lower	Open colorectal resection. The anastomotic line in the low segment approximately 0-5 cm from the anal verge.
Group 2: Open Surgery Middle/Upper	Open colorectal resection. The anastomotic line in the middle/upper segment 5-12 cm from the anal verge.
Group 3: Laparoscopic Surgery Lower	Laparoscopic colorectal resection. The anastomotic line in the low segment approximately 0-5 cm from the anal verge.
Group 4: Laparoscopic Surgery Middle/Upper	Laparasocopic colorectal resection. The anastomotic line in the mid/upper segment 5-12 cm from the anal verge.

Participant Flow: Overall Study

	Group 1: Open Surgery Lower	Group 2: Open Surgery Middle/Upper	Group 3: Laparoscopic Surgery Lower	Group 4: Laparoscopic Surgery Middle/Upper
STARTED	**7**	**9**	**4**	**5**
COMPLETED	**7**	**9**	**4**	**5**
NOT COMPLETED	**0**	**0**	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Group 1: Open Surgery Lower	No text entered.
Group 2: Open Surgery Middle/Upper	No text entered.
Group 3: Laparoscopic Surgery Lower	No text entered.
Group 4: Laparoscopic Surgery Middle/Upper	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Group 1: Open Surgery Lower	Group 2: Open Surgery Middle/Upper	Group 3: Laparoscopic Surgery Lower	Group 4: Laparoscopic Surgery Middle/Upper	Total
Number of Participants [units: participants]	**7**	**9**	**4**	**5**	**25**
Age [units: years] Mean (Standard Deviation)	**63.7 (8.5)**	**64.6 (12.8)**	**68.5 (9.9)**	**65.2 (12.0)**	**65.1 (10.6)**

Gender [units: participants]					
Female	0	3	0	5	8
Male	7	6	4	0	17

Outcome Measures

Show All Outcome Measures

1. Primary: The Primary Endpoint is the Feasibility of the TachoSil® Application, Reported by the Combined Assessment of the Investigator and External Assessor [Time Frame: Day of surgery]

Show Outcome Measure 1

2. Secondary: The Secondary Endpoint is the Feasibility of the TachoSil® Application, Assessed by the Investigator. [Time Frame: Day of surgery]

Show Outcome Measure 2

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** After publication of the results or 24 months after Clinical Trial Report has been finalised, whichever comes

first, Nycomed acknowledge the Investigator's rights to publish results from this trial. Any such scientific paper, presentation, communication, or other information concerning the investigation described in this protocol, must be submitted to Nycomed prior to submission for publication/presentation for review. Review comments will be given within a month from receipt of the manuscript.

Results Point of Contact:

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Responsible Party:	Nycomed
ClinicalTrials.gov Identifier:	NCT00713661 History of Changes
Other Study ID Numbers:	**TC-029-IM**
	2007-007254-62 (EudraCT Number)
Study First Received:	July 7, 2008
Results First Received:	December 20, 2011
Last Updated:	May 4, 2012
Health Authority:	Germany: Ethics Commission
	The Netherlands:
	United Kingdom:

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