TachoSil® Versus Standard Haemostatic Treatment of Haemorrhage in Cardiovascular Surgery (TC-023-IM)

This study has been completed.

Sponsor:
Nycomed

Information provided by:
Nycomed

ClinicalTrials.gov Identifier:
NCT00440401

First received: February 26, 2007
Last updated: May 4, 2012
Last verified: July 2010
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: May 7, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Haemorrhage Haemostasis Cardiovascular Surgery
Interventions:	Drug: fibrinogen (human) + thrombin (human) Drug: Standard haemostatic treatment in cardiovascular surgery

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
From the total of 120 enrolled subjects, data are presented for 119 randomised subjects that received trial treatment (= Intention to Treat (ITT) population).

Reporting Groups

	Description

TachoSil®	Absorbable sponge for intra-operative topical application
Comparator	Standard haemostatic treatment in cardiovascular surgery

Participant Flow: Overall Study

	TachoSil®	Comparator
STARTED	**59**	**60**
COMPLETED	**55**	**54**
NOT COMPLETED	**4**	**6**
Adverse Event	**2**	**1**
Not specified	**2**	**5**

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
TachoSil®	No text entered.
Standard Treatment	No text entered.
Total	Total of all reporting groups

Baseline Measures

	TachoSil®	Standard Treatment	Total
Number of Participants [units: participants]	**59**	**60**	**119**
Age, Customized [units: participants]			
18-65 years	**24**	**21**	**45**
65 years or above	**35**	**39**	**74**
Gender [units: participants]			
Female	**14**	**17**	**31**
Male	**45**	**43**	**88**
Race/Ethnicity, Customized [1] **[units: participants]**			
Caucasian	**59**	**60**	**119**
Classification of surgery [2] **[units: Percentage of subjects]**	**44**	**59**	**103**

Evaluation of bleeding at target area before randomization [3] [units: participants]			
Arterial	**48**	**40**	**88**
Venous	**11**	**20**	**31**
Mild haemorrhage	**19**	**24**	**43**
Moderate haemorrhage	**35**	**34**	**69**
Severe haemorrhage	**5**	**2**	**7**
Identification of target area for efficacy evaluation [4] [units: participants]			
Aorta	**35**	**32**	**67**
Coronary anastomosis	**2**	**3**	**5**
Internal mammary artery vascular bed	**1**	**1**	**2**
Left atrium	**3**	**2**	**5**
Left ventricle	**3**	**2**	**5**
Right atrium	**5**	**10**	**15**
Right ventricle	**11**	**8**	**19**
Other	**3**	**2**	**5**
Primary haemostatic treatment [5] [units: participants]			
Suturing	**43**	**43**	**86**
Electro-coagulation	**6**	**5**	**11**
Clips	**3**	**2**	**5**
Gauze	**0**	**1**	**1**
None	**10**	**12**	**22**
Type of tissue [6] [units: participants]			
Tissue	**16**	**22**	**38**
Vessel	**43**	**38**	**81**

[1] All patients were Caucasian

[2] Planned elective surgery on the heart, the ascending aorta or arch, requiring cardiopulmonary bypass procedure.

The information about planned surgery reflects the protocol defined eligibility criterion no. 5. In addition, the actually performed surgery is categorized into simple and combined/complex cardiovascular procedures. The proportions of patients undergoing combined/complex cardiovascular procedures in the TachoSil® group and the Standard Treatment group, respectively, were 44 and 59 percent. The calculated total (103) is irrelevant and inappropriate arithmetic.

[3] In order to avoid selection bias, evaluation of bleeding at target area was performed after completion of primary hemostasis and prior to randomization.

Data obtained prior to final assessment of patient eligibility and randomization.

More than one record/condition per patient possible.

[4] In order to avoid selection bias, intra-operative randomization was only performed if supportive haemostatic treatment was required after completion of primary haemostasis.

Data obtained prior to final assessment of patient eligibility and randomization.

More than one record/condition per patient possible.

[5] Data obtained prior to final assessment of patient eligibility and randomization.

More than one record/condition per patient possible.

[6] Type of tissue treated with randomized treatment

Outcome Measures

Show All Outcome Measures

1. Primary: Proportion of Subjects Achieving Haemostasis at 3 Minutes [Time Frame: 3 minutes]

Show Outcome Measure 1

2. Secondary: Proportion of Subjects Achieving Haemostasis at 6 Minutes. [Time Frame: 6 minutes]

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.

Results Point of Contact:

Name/Title: Medical Responsible
Organization: Medical Scientific Strategy

phone: +45 4677 1111
e-mail: clinicaltrials@nycomed.com

Responsible Party:	Nycomed, Clinical Trial Operations
ClinicalTrials.gov Identifier:	NCT00440401 History of Changes
Other Study ID Numbers:	**TC-023-IM**
Study First Received:	February 26, 2007
Results First Received:	May 7, 2010
Last Updated:	May 4, 2012
Health Authority:	Germany: Paul-Ehrlich-Institut

TO TOP

For Patients and Families | **For Researchers** | **For Study Record Managers**

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK