TASALL - TachoSil® Against Liquor Leak

This study has been completed.

Sponsor:
Takeda

Information provided by (Responsible Party):
Takeda

ClinicalTrials.gov Identifier:
NCT01355627

First received: May 11, 2011
Last updated: June 26, 2014
Last verified: June 2014
History of Changes

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Results First Received: June 26, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Cerebrospinal Fluid Leaks
Interventions:	Procedure: TachoSil® Procedure: Current Practice

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
Participants took part in the study at thirty-five Centres in a total of 10 countries: Belgium, France, Germany, Greece, Italy The Netherlands, Poland, Russia, Spain and Sweden from 28 April 2011 to 27 June 2013.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants requiring dura sealing techniques for the prevention of post-operative cerebrospinal fluid (CSF) leaks were enrolled; 726 participants were randomized equally in 1 of 2 treatment groups, TachoSil® or Current practice group.

Reporting Groups

	Description
TachoSil®	Primary suture was performed. Duraplasty could be performed at the discretion of the investigator. TachoSil® was

	applied under aseptic conditions during the closure of the dura.
Current Practice Group	Primary suture was performed. Duraplasty could be performed at the discretion of the investigator. In addition to primary suture, whatever means of dura closure treatment, alone or in combination, as deemed necessary by the investigator was used with the exception of TachoSil®.

Participant Flow: Overall Study

	TachoSil®	Current Practice Group
STARTED	**362**	**364**
Safety Analysis Set	**362**	**364**
Full Analysis Set	**361** [1]	**365** [2]
COMPLETED	**329**	**326**
NOT COMPLETED	**33**	**38**
Request By the Patient to Discontinue	**5**	**7**
Lost to Follow-up	**8**	**7**
Fatal Adverse Event	**19**	**23**
Other	**1**	**1**

[1] One participant's data for final follow-up is missing, completion status could not be confirmed.
[2] One participant randomized to Current Practice actually received TachoSil®.

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.
Baseline Measures were based on the Full Analysis Set that included all enrolled randomized patients.

Reporting Groups

	Description
TachoSil®	Primary suture was performed. Duraplasty could be performed at the discretion of the investigator. TachoSil® was applied under aseptic conditions during the closure of the dura.
Current Practice Group	Primary suture was performed. Duraplasty could be performed at the discretion of the investigator. In addition to primary suture, whatever means of dura closure treatment, alone or in combination, as deemed necessary by the investigator was used with the exception of TachoSil®.
Total	Total of all reporting groups

Baseline Measures

	TachoSil®	Current Practice Group	Total
Number of Participants [units: participants]	**361**	**365**	**726**
Age [units: years] Mean (Standard Deviation)	**53.1 (13.80)**	**53.2 (14.22)**	**53.1 (14.00)**
Age, Customized [units: participants]			

18-65 years	288	293	581
>65 years	73	72	145
Gender [units: participants]			
Female	233	211	444
Male	128	154	282
Race/Ethnicity, Customized [units: participants]			
White/Caucasian	355	361	716
Asian	1	0	1
Black or African American	3	2	5
American Indian or Alaska Native	1	1	2
Other	1	1	2
Race/Ethnicity, Customized [units: participants]			
Hispanic or Latino	55	62	117
Non-Hispanic and Non-Latino	295	289	584
Unknown	11	14	25
Region of Enrollment [units: participants]			
Belgium	87	87	174
Germany	33	29	62
Spain	54	54	108
France	24	26	50
Greece	34	38	72
Italy	14	14	28
Netherlands	3	2	5
Poland	59	61	120
Russian Federation	9	8	17
Sweden	44	46	90
Height [units: cm] Mean (Standard Deviation)	167.4 (9.44)	168.5 (9.18)	168.0 (9.32)
Weight [units: kg] Mean (Standard Deviation)	73.6 (14.40)	75.2 (16.79)	74.4 (15.65)
Body Mass Index (BMI) [units: kg/m^2] Mean (Standard Deviation)	26.20 (4.44)	26.42 (5.10)	26.31 (4.79)
Fertility Status [units: participants]			
Fertile	74	74	148

Post-Menopausal	**140**	**111**	**251**
Surgically Sterile	**19**	**26**	**45**
Not Applicable	**128**	**154**	**282**

Outcome Measures

Show All Outcome Measures

1. Primary: Percentage of Participants With Clinically Evident Verified Post-Operative Cerebrospinal Fluid Leak or Clinically Evident Pseudomeningocele or Treatment Failure [Time Frame: Up to 8 Weeks (7 Weeks ± 1 Week)]

Show Outcome Measure 1

2. Secondary: Percentage of Participants With Post-Surgical Non-Clinically Evident Post-Operative Pseudomeningocele [Time Frame: Assessment at least once prior to discharge from neurosurgical ward, with the expected discharge from neurosurgical ward after an average of 10 days (Up to 28 Weeks)]

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
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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:** The first study related publication will be a multi-center publication submitted within 24 months after conclusion

or termination of a study at all sites. After such multi site publication, all proposed site publications and presentations will be submitted to sponsor for review 60 days in advance of publication. Site will remove Sponsor confidential information unrelated to study results. Sponsor can delay a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact:

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Responsible Party:	Takeda
ClinicalTrials.gov Identifier:	NCT01355627 History of Changes
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Results First Received:	June 26, 2014
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Health Authority:	Austria: Ethikkommission Belgium: Federal Agency for Medicinal Products and Health Products France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Paul-Ehrlich-Institut Greece: National Organization of Medicines Italy: The Italian Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Russia: Ethics Committee Spain: Agencia Española de Medicamentos y Productos Sanitarios Sweden: Regional Ethical Review Board

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