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Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

Fibrin Sealant for the Sealing of Dura Sutures

This study has been completed.

Sponsor:
Baxter Healthcare Corporation

Information provided by (Responsible Party):
Baxter Healthcare Corporation

ClinicalTrials.gov Identifier:
NCT00681824

First received: May 19, 2008
Last updated: May 21, 2013
Last verified: May 2013
History of Changes

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

Results First Received: March 12, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Pathological Processes in the Posterior Fossa Dura Defects
Interventions:	Biological: Fibrin Sealant, Vapor Heated, Solvent/Detergent-treated with 500 IU/mL thrombin and synthetic aprotinin (FS VH S/D 500 Procedure: Standard of care

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 were enrolled at 12 United States and 1 Canadian clinical site(s) beginning May 2008 and completing in March 2010

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
95 were enrolled. 23 discontinued (10 screen failures, 3 withdrawn by investigator, 3 withdrawn by representative or self, 1 died- failure to thrive, 1 had surgery before randomized, 1 study site distance, 1 site reached enrollment goal, 2 patients cancelled surgery, 1 family delayed >30 day window. 62 randomized. There were 13 run-in participants.

Reporting Groups

	Description
Standard of Care	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
Run-in Participants: FS VH S/D 500 S-apr	One initial
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes.

Participant Flow: Overall Study

	Standard of Care	Run-in Participants: FS VH S/D 500 S-apr	FS VH S/D 500 S-apr
STARTED	**28**	**13**	**34**
COMPLETED	**27**	**12**	**33**
NOT COMPLETED	**1**	**1**	**1**
withdrawn by investigator	**0**	**0**	**1**

scheduling conflict	**1**	**0**	**0**
Death	**0**	**1**	**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.
Primary Safety Dataset Note: This includes 13 initial "run-in" participants in the FS VH S/D 500 s-apr arm (one for each site permitted to familiarize the investigators with the study procedures)

Reporting Groups

	Description
Standard of Care (SoC)	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr (Run-In Participants Only)	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group only includes the 13 initial "run-in" participants (one for each site permitted to familiarize the investigators with the study procedures)
FS VH S/D 500 S-apr (Non Run-In Participants Only)	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group does not include the 13 initial "run-in" participants (one for each site permitted to familiarize the investigators with the study procedures)
Total	Total of all reporting groups

Baseline Measures

	Standard of Care (SoC)	FS VH S/D 500 S-apr (Run-In Participants Only)	FS VH S/D 500 S-apr (Non Run-In Participants Only)	Total
Overall Participants [units: participants]	**28**	**13**	**34**	**75**
Age [units: years] Mean (Standard Deviation)	**40.2 (19.7)**	**42.9 (20.34)**	**33.3 (19.01)**	**37.5 (19.6)**
Gender [units: participants]				
Female	**17**	**10**	**21**	**48**
Male	**11**	**3**	**13**	**27**
Region of Enrollment [units: participants]				
United States	**25**	**12**	**30**	**67**
Canada	**3**	**1**	**4**	**8**

Outcome Measures

Hide All Outcome Measures

1. Primary: Incidence of Cerebrospinal Fluid (CSF) Leakage Observed After Surgery [Time Frame: 33 +/- 3 days after surgery]

Measure Type	Primary
Measure Title	Incidence of Cerebrospinal Fluid (CSF) Leakage Observed After Surgery
Measure Description	Study-relevant CSF leakage is defined as one or more of following: 1. Discrete subcutaneous or subgaleal CSF collection (pseudomeningocele) in surgical area confirmed by positive

	test for β2-transferrin, or by computed tomography (CT) or magnetic resonance imaging (MRI) 2. Epidural CSF collection in surgical area depicted by CT or MRI 3. Leakage of CSF through surgical wound observed during physical examination, confirmed by a positive test for β2-transferrin 4. Progressive pneumatocephalus (air in subarachnoidal space) depicted by repeat CT in absence of CSF drainage.
Time Frame	33 +/- 3 days after surgery
Safety Issue	No

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.
Intent to treat One participant (SoC arm) received products other than FS VH S/D 500 s-apr for sealing of dura sutures and was removed from analysis Two participants (FS VH S/D 500 s-apr arm) removed from analysis due to (1) subsequent surgery unrelated to CSF leakage/surgical site infection that involved re-durotomy (2) withdrew from study

Reporting Groups

	Description
Standard of Care (SoC)	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group does not include 13 initial run-in participants (one for each site permitted to familiarize the investigators with the study procedures)

Measured Values

	Standard of Care (SoC)	**FS VH S/D 500 S-apr**

Overall Participants [units: participants]	**27**	**32**
Incidence of Cerebrospinal Fluid (CSF) Leakage Observed After Surgery [units: percentage of participants] Number (95% Confidence Interval)	**74.07** **(55.32 to 86.83)**	**78.13** **(61.25 to 88.98)**

Statistical Analysis 1 for Incidence of Cerebrospinal Fluid (CSF) Leakage Observed After Surgery

Groups [1]	All groups
Method [2]	likelihood ratio of chi squared test
P Value [3]	0.7159

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Primary: Number of Participants With Cerebrospinal Fluid (CSF) Leakage Observed After Surgery [Time Frame: 33 +/- 3 days after surgery]

Measure Type	Primary
Measure Title	Number of Participants With Cerebrospinal Fluid (CSF) Leakage Observed After Surgery

Measure Description	Study-relevant CSF leakage is defined as one or more of following: 1. Discrete subcutaneous or subgaleal CSF collection (pseudomeningocele) in surgical area confirmed by positive test for β2–transferrin, or by computed tomography (CT) or magnetic resonance imaging (MRI) 2. Epidural CSF collection in surgical area depicted by CT or MRI 3. Leakage of CSF through surgical wound observed during physical examination, confirmed by a positive test for β2–transferrin 4. Progressive pneumatocephalus (air in subarachnoidal space) depicted by repeat CT in absence of CSF drainage.
Time Frame	33 +/- 3 days after surgery
Safety Issue	No

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.
Intent to treat One participant (SoC arm) received products other than FS VH S/D 500 s-apr for sealing of dura sutures and was removed from analysis Two participants (FS VH S/D 500 s-apr arm) removed from analysis due to (1) subsequent surgery unrelated to CSF leakage/surgical site infection that involved re-durotomy (2) withdrew from study

Reporting Groups

	Description
Standard of Care (SoC)	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group does not include 13 initial run-in participants (one for each site permitted to familiarize the investigators with the study procedures)

Measured Values

	Standard of Care (SoC)	FS VH S/D 500 S-apr
Overall Participants [units: participants]	**27**	**32**
Number of Participants With Cerebrospinal Fluid (CSF) Leakage Observed After Surgery [units: participants]	**20**	**25**

No statistical analysis provided for Number of Participants With Cerebrospinal Fluid (CSF) Leakage Observed After Surgery

3. Secondary: Incidence of Procedures Resulting From the Treatment of CSF Leaks [Time Frame: until resolution or 30 days after final follow-up visit (Day 33+/-3), whichever is first]

Measure Type	Secondary
Measure Title	Incidence of Procedures Resulting From the Treatment of CSF Leaks
Measure Description	The incidence of surgical revisions, number and duration of compression bandage applications and of liquor drainage procedures
Time Frame	until resolution or 30 days after final follow-up visit (Day 33+/-3), whichever is first
Safety Issue	No

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.
Intent to treat One participant (SoC arm) received products other than FS VH S/D 500 s-apr for sealing of dura sutures and was removed from analysis One participant (FS VH S/D 500 s-apr arm) removed from analysis due to subsequent surgery unrelated to CSF leakage/surgical site infection that involved re-durotomy

Reporting Groups

	Description
Standard of Care (SoC)	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group does not include 13 initial run-in participants (one for each site permitted to familiarize the investigators with the study procedures)

Measured Values

	Standard of Care (SoC)	FS VH S/D 500 S-apr
Overall Participants [units: participants]	**27**	**33**
Incidence of Procedures Resulting From the Treatment of CSF Leaks [units: percentage of participants] Number (95% Confidence Interval)		
Surgical Revision	**0** [1]	**3.03** **(0.54 to 15.32)**
Compression Bandage	**0** [1]	**0** [1]
Liquor Drainage	**0** [1]	**0** [1]

[1] There were no procedures for this group

No statistical analysis provided for Incidence of Procedures Resulting From the Treatment of CSF Leaks

4. Secondary: Number of Participants With Procedures Resulting From the Treatment of CSF Leaks [Time Frame: until resolution or 30 days after final follow-up visit (Day 33+/-3), whichever is first]

Measure Type	Secondary
Measure Title	Number of Participants With Procedures Resulting From the Treatment of CSF Leaks
Measure Description	The number of participants with surgical revisions, number and duration of compression bandage applications and of liquor drainage procedures.
Time Frame	until resolution or 30 days after final follow-up visit (Day 33+/-3), whichever is first
Safety Issue	No

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.
Intent to treat One participant (SoC arm) received products other than FS VH S/D 500 s-apr for sealing of dura sutures and was removed from analysis One participant (FS VH S/D 500 s-apr arm) removed from analysis due to subsequent surgery unrelated to CSF leakage/surgical site infection that involved re-durotomy

Reporting Groups

	Description
Standard of Care (SoC)	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group does not include 13 initial run-in participants (one for each site permitted to familiarize the investigators with the study procedures)

Measured Values

	Standard of Care (SoC)	**FS VH S/D 500 S-apr**

Overall Participants [units: participants]	**27**	**33**
Number of Participants With Procedures Resulting From the Treatment of CSF Leaks [units: participants]		
Surgical Revision	**0**	**1**
Compression Bandage	**0**	**0**
Liquor Drainage	**0**	**0**

No statistical analysis provided for Number of Participants With Procedures Resulting From the Treatment of CSF Leaks

5. Secondary: Incidence of Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria [Time Frame: within 1 month following surgery]

Measure Type	Secondary
Measure Title	Incidence of Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria
Measure Description	No text entered.
Time Frame	within 1 month following surgery
Safety Issue	Yes

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.
Primary Safety Data Set One participant (FS VH S/D 500 s-apr arm) removed from analysis due to subsequent surgery unrelated to CSF leakage/surgical site infection that involved re-durotomy

Reporting Groups

	Description
Standard of Care	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group includes 13 initial run-in participants (one for each site permitted to familiarize the investigators with the study procedures)

Measured Values

	Standard of Care	FS VH S/D 500 S-apr
Overall Participants [units: participants]	**28**	**46**
Incidence of Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria [units: percentage of participants] Number (95% Confidence Interval)	**0.00** [1]	**2.17** **(0.38 to 11.34)**

[1] There were no SSIs for this group

No statistical analysis provided for Incidence of Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria

6. Secondary: Number of Participants With Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria
[Time Frame: within 1 month following surgery]

Measure Type	Secondary

Measure Title	Number of Participants With Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria
Measure Description	No text entered.
Time Frame	within 1 month following surgery
Safety Issue	Yes

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.
Primary Safety Data Set One participant (FS VH S/D 500 s-apr arm) removed from analysis due to subsequent surgery unrelated to CSF leakage/surgical site infection that involved re-durotomy

Reporting Groups

	Description
Standard of Care	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group includes 13 initial run-in participants (one for each site permitted to familiarize the investigators with the study procedures)

Measured Values

	Standard of Care	**FS VH S/D 500 S-apr**
Overall Participants [units: participants]	**28**	**46**

Number of Participants With Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria [units: participants]	**0**	**1**

No statistical analysis provided for Number of Participants With Surgical Site Infections (SSI) According to National Nosocomial Infection Surveillance (NNIS) Criteria

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Throughout the study period, 1 year and 10 months
Additional Description	No text entered.

Reporting Groups

	Description
Standard of Care (SoC)	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
FS VH S/D 500 S-apr	Application of thin layer of FS VH S/D 500 s-apr to entire length of suture loop and adjacent area to at least 5 mm away from the suture line, including all suture holes. After application, the product is to be allowed to polymerize for 3 minutes. Note: This arm/group includes 13 initial "run-in" participants (one for each site permitted to familiarize the investigators with the study procedures)

Serious Adverse Events

	Standard of Care (SoC)	**FS VH S/D 500 S-apr**
Total, serious adverse events		
# participants affected / at risk	**4/28 (14.29%)**	**10/47 (21.28%)**

General disorders		
Facial pain [1]		
# participants affected / at risk	**1/28 (3.57%)**	**0/47 (0.00%)**
# events	**1**	**0**
Injury, poisoning and procedural complications		
Intracranial hypotension [1]		
# participants affected / at risk	**0/28 (0.00%)**	**2/47 (4.26%)**
# events	**0**	**2**
Post procedural complication [1]		
# participants affected / at risk	**0/28 (0.00%)**	**1/47 (2.13%)**
# events	**0**	**1**
Pseudomeningocele [1]		
# participants affected / at risk	**0/28 (0.00%)**	**2/47 (4.26%)**
# events	**0**	**2**
Metabolism and nutrition disorders		
Failure to thrive [1]		
# participants affected / at risk	**0/28 (0.00%)**	**1/47 (2.13%)**
# events	**0**	**1**
Nervous system disorders		
Cerebellar haemorrhage [1]		
# participants affected / at risk	**0/28 (0.00%)**	**1/47 (2.13%)**
# events	**0**	**1**
Hydrocephalus [1]		
# participants affected / at risk	**0/28 (0.00%)**	**2/47 (4.26%)**
# events	**0**	**2**
Meningitis aseptic [1]		
# participants affected / at risk	**0/28 (0.00%)**	**1/47 (2.13%)**
# events	**0**	**1**
Psychiatric disorders		

Affect lability [1]		
# participants affected / at risk	**0/28 (0.00%)**	**1/47 (2.13%)**
# events	**0**	**1**
Mental status changes [1]		
# participants affected / at risk	**1/28 (3.57%)**	**0/47 (0.00%)**
# events	**1**	**0**
Respiratory, thoracic and mediastinal disorders		
Pulmonary oedema [1]		
# participants affected / at risk	**0/28 (0.00%)**	**1/47 (2.13%)**
# events	**0**	**1**
Pulmonary embolism [1]		
# participants affected / at risk	**1/28 (3.57%)**	**0/47 (0.00%)**
# events	**1**	**0**
Skin and subcutaneous tissue disorders		
Rash [1]		
# participants affected / at risk	**0/28 (0.00%)**	**1/47 (2.13%)**
# events	**0**	**1**
Vascular disorders		
Deep vein thrombosis [1]		
# participants affected / at risk	**1/28 (3.57%)**	**1/47 (2.13%)**
# events	**1**	**1**

1 Term from vocabulary, MedDRA (Unspecified)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Throughout the study period, 1 year and 10 months

Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Standard of Care (SoC)	The closure of a dura defect by suturing in a patch of autologous fascia, pericranium or suturable collagen-based dura substitute.
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Other Adverse Events

	Standard of Care (SoC)	FS VH S/D 500 S-apr
Total, other (not including serious) adverse events		
# participants affected / at risk	**20/28 (71.43%)**	**33/47 (70.21%)**
Eye disorders		
Diplopia [1]		
# participants affected / at risk	**3/28 (10.71%)**	**0/47 (0.00%)**
# events	**3**	**0**
Gastrointestinal disorders		
Nausea [1]		
# participants affected / at risk	**6/28 (21.43%)**	**5/47 (10.64%)**
# events	**6**	**5**
Vomiting [1]		
# participants affected / at risk	**3/28 (10.71%)**	**2/47 (4.26%)**

# events	3	2
General disorders		
Pyrexia [1]		
# participants affected / at risk	0/28 (0.00%)	5/47 (10.64%)
# events	0	5
Infections and infestations		
Candidiasis [1]		
# participants affected / at risk	2/28 (7.14%)	0/47 (0.00%)
# events	2	0
Urinary tract infection [1]		
# participants affected / at risk	1/28 (3.57%)	3/47 (6.38%)
# events	1	3
Injury, poisoning and procedural complications		
Incision site pain [1]		
# participants affected / at risk	15/28 (53.57%)	25/47 (53.19%)
# events	15	25
Pseudomeningocele [1]		
# participants affected / at risk	2/28 (7.14%)	1/47 (2.13%)
# events	2	1
Metabolism and nutrition disorders		
Hypomagnesaemia [1]		
# participants affected / at risk	2/28 (7.14%)	1/47 (2.13%)
# events	2	1
Nervous system disorders		
Balance disorder [1]		
# participants affected / at risk	2/28 (7.14%)	0/47 (0.00%)
# events	2	0
Headache [1]		
# participants affected / at risk	1/28 (3.57%)	4/47 (8.51%)

# events	**2**	**4**
Vascular disorders		
Hypertension [1]		
# participants affected / at risk	**2/28 (7.14%)**	**5/47 (10.64%)**
# events	**2**	**5**

1 Term from vocabulary, MedDRA (Unspecified)

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:** Baxter's agreements with PIs may vary per requirements of individual PI, but contain common elements. For this study, PIs are restricted from independently publishing results until the earlier of the primary multicenter publication or 12 months after study completion. Baxter requires a review of results communications (e.g., for confidential information) ≥45 days prior to submission or communication. Baxter may request an additional delay of ≤60 days e.g., for intellectual property protection)

Results Point of Contact:

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Responsible Party:	Baxter Healthcare Corporation
ClinicalTrials.gov Identifier:	NCT00681824 History of Changes
Other Study ID Numbers:	550701
Study First Received:	May 19, 2008
Results First Received:	March 12, 2013
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