The Surpass intracranial aneurysm embolization system pivotal trial to treat large or giant wide neck aneurysms

Published: 25-01-2013
Last updated: 26-04-2024

The objective of this study is to determine the safety and effectiveness of the Surpass NeuroEndoGraft* System in the endovascular treatment of large or giant wide-necked intracranial aneurysms (IA) in internal carotid artery up to the terminus.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON39950

Source
ToetsingOnline

Brief title
SCENT

Condition

- Aneurysms and artery dissections

Synonym
aneurysm, bulge

Research involving
Human

Sponsors and support

Primary sponsor: Boston Biomedical Associates
Source(s) of monetary or material Support: Stryker,Stryker Neurovascular

Intervention

Keyword: intracranial aneurysm, large or wide neck aneurysms

Outcome measures

Primary outcome

The primary efficacy endpoint is the percent of subjects with 100% occlusion (Raymond Class 1) without clinically significant stenosis (defined as < 50% stenosis) of the parent artery based on core lab evaluation of the 12 month follow up angiogram and without any subsequent treatment at the target aneurysm at the 12 month follow up visit

Secondary outcome

The secondary safety endpoint is the percent of subjects experiencing one or more serious adverse events (SAE) through 12 months post-index procedure within the following categories (see definitions section of this protocol), as adjudicated by the Clinical Events Committee (CEC).

• Proportion of subjects with new or worsening major ipsilateral stroke

• Proportion of subjects experiencing acute or subacute (<6 weeks) thrombosis of the Surpass Implant

In addition to evaluating the secondary safety endpoint in the categories described above, all adverse events will be reported as individual rates.

4.5.2 Efficacy

The secondary effectiveness endpoints identified below will be assessed post-index procedure annually (at 12, 24, 36, 48, 60 months) for up to 60 months:

• Rate of aneurysm rupture

• Surpass Implant stenosis (>=50% stenosis of flow diverter)

• Parent artery occlusion at the target aneurysm location (>=50% stenosis)

• Functional status: change in the modified Rankin score compared to baseline

• Technical success: defined as the proportion of subjects in whom the Surpass implant(s) was delivered to cover the aneurysm neck.

• Proportion of subjects with Raymond Class 1, 2 and 3 at 6 months

• Proportion of subjects with complete occlusion at 6 months

• Incidence of retreatment (with Surpass System or otherwise) at 6, 12, 24 and up to 60 months

• Surpass Flow Diverter success: implant successfully delivered to the target location

Study description

Background summary

Stroke is the most common life-threatening neurological disease, the third leading cause of death in the United States, and 795,000 people suffer a new or recurrent stroke each year. Hemorrhage is responsible for 13% of these events and the majority of these are related to rupture of intracranial aneurysms. The incidence of unruptured intracranial aneurysms in the general population has been estimated to range from approximately 2% up to 6%. The most common presentation of an intracranial aneurysm is a subarachnoid hemorrhage (SAH) secondary to aneurysm rupture, a devastating medical emergency, with an annual incidence in North America of approximately 12 per 100,000. In a minority of patients, aneurysms can be diagnosed before rupturing, usually because of screening related to family history or concomitant associated disease. In addition, an increasing number of patients have aneurysms diagnosed as incidental findings during neuroimaging for another indication (carotid/cerebral angiography, magnetic resonance imagining (MRI) or computer tomography (CT)). If left untreated these aneurysms could lead to a neurological event or death.

Study objective

The objective of this study is to determine the safety and effectiveness of the Surpass NeuroEndoGraft* System in the endovascular treatment of large or giant wide-necked intracranial aneurysms (IA) in internal carotid artery up to the terminus.

Study design

The Surpass IntraCranial Aneurysm EmbolizatioN System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (SCENT) is a multi-center, prospective, non-randomized trial to evaluate the safety and effectiveness of the Surpass Flow Diverter..
The study will initially include approximately 100 subjects treated with the Surpass Flow Diverter. Following evaluation of the first 40 subjects at 6 months, an adaptive sample size approach will set the final sample size for the SCENT trial between 100 and 180. Those physicians that have not used the study device in a clinical setting will complete 1-3 roll-in cases before completing a study case, allowing for a total of 45 roll-in cases. Subjects in the roll-in cohort are not included in the target sample of 100 to 180 treated subjects.
Subjects are considered enrolled once they sign the informed consent.
All enrolled subjects that have the study device inserted in their body, regardless of whether or not implantation of the device takes place, will undergo post procedure follow up evaluations at one (1) month, six (6) months, and twelve (12) months. All subjects that have the study device implanted will continue to be followed annually for sixty (60) months post-procedure.
Enrolled subjects that have the pre-procedure angiogram performed but do not have the study device enter their body will be followed for thirty days. This subject population will be referred to as *enrolled, not treated, angio* (ENTa). Subjects that are enrolled but exit the study before the pre-procedure angiogram will be referred to as *enrolled, not treated, no angio* (ENTna). Enrolled subjects that are found to not be eligible to participate in the study after signing the consent form, will be exited from the study at determination of ineligibility
After the completion of the 12 month follow up evaluation, Stryker will submit a Pre-market Approval (PMA) application to FDA, which will include SCENT data to establish the safety and efficacy of the device. All subjects enrolled in this pivotal study will continue to be followed according to this protocol and regular annual reports will be submitted to FDA.
This study incorporates a rigorous design that involves the use of an independent Clinical Events Committee (CEC), an angiographic core lab and study monitors will confirm neurological assessments, all adverse events and study data with source documentation.

Intervention

The device is called the Surpass Flow Diverter and is intended to treat large

or giant wide neck intracranial aneurysms.

Study burden and risks

The study is designed to minimize potential risks and complications in the subjects. Risks associated with using the Surpass Flow Diverter are believed to be similar as those associated with intracranial catheterization or intracranial stent placement. The following risks associated with intracranial catheterization or intracranial stent placements have been identified as possible (anticipated) risks and may occur:
• Aneurysm recanalization
• Aneurysm enlargement
• Allergic reaction including, but not limited to, contrast medium, metals (cobalt chromium, platinum and tungsten) and medications
• Arrhythmia
• Arteriovenous fistula
• Confusion, coma, loss of consciousness or other change in mental status
• Death
• Detachment of a component of the system
• Device migration / embolization
• Device thrombosis / occlusion
• Emboli (air, tissue or thrombotic emboli)
• Emergent neurosurgery
• Failure to deliver the Device to the intended site
• Headache
• Hemorrhage including intracranial, vascular, peritoneal, and groin
• Hematoma
• Hypotension / hypertension
• Hydrocephalous
• Incomplete aneurysm occlusion
• Infection
• Injury to normal vessels or tissue
• Ischemia
• Mass effect
• Myocardial infarction
• Nausea
• Neurologic deficit
• Occlusion of side branch
• Pain at insertion site
• Perforation of aneurysm
• Pseudoaneurysm
• Renal failure
• Reaction due to radiation exposure
• Rupture, vessel or aneurysm
• Seizures
• Stenosis of treated segment
• Stroke / TIA / cerebrovascular accident - new or worsening of symptoms

• Total occlusion of treated segment
• Vasospasm
• Vision impairment/blindness
• Vessel dissection or perforation
• Vessel thrombosis/occlusion
• Vomiting

Possible benefits:

• Less cases of ruptures
• The ability to large and wide neck aneurysms leads to treatment with fewer resources by the available sizes of the Surpass-tool.

Contacts

Public
Boston Biomedical Associates

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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

age 19-80 years
subject has a single targeted intracranial aneurysm that:
- located in the internal carotid artery distribution up to the terminus
-is able to cross with a standard 0,014"guide wire
-has a neck > 4mm or no discernible neck and an aneurysm size > 10mm

Exclusion criteria

- known allergy or contraindication to Aspirin, Clopidogrel/Plavix, heparin,local or general anesthesia.
- known history of life threathening allergy to contrast dye
- More than one intracranial aneurysm that requires treatment within 12 months
- unstable neurological deficit
- extra-cranial stenosis or parent vessel with stenosis > 50% in the area proximal to the aneurysm

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Surpass Flow Diverter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-01-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL41777.091.12