EUROPEAN ECLIPSTM SAFETY, FEASIBILITY AND EFFICACY STUDY (EESIS) PROTOCOL
A multi-center post marketing study evaluating the safety, technical feasibility, and efficacy of the eCLIPsTM Family of Products for the treatment of bifurcation intracranial aneurysms.

Published: 17-02-2016
Last updated: 19-04-2024

To provide preliminary technical feasibility, safety and efficacy data foreCLIPs Family of products.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON42694

Source
ToetsingOnline

Brief title
EESIS

Condition

- Central nervous system vascular disorders
- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
aneurysm, bulge

Research involving
Human

Sponsors and support

Primary sponsor: Evasc
Source(s) of monetary or material Support: Evasc

Intervention

Keyword: intracranial aneurysm

Outcome measures

Primary outcome

1. Safety End Point: absence of a major territorial stroke or death

within 30 days (procedural).

2. Safety End Point: absence of a major territorial stroke or

neurological death between 31 days and 12 months

3. Efficacy End Point: complete aneurysm occlusion (Raymond 1)

at 6 months

4. Efficacy End Point: complete aneurysm occlusion (Raymond 1)

at 12 months

Secondary outcome

1. eCLIPs Bifurcation Remodeling System Technical Success:

measured by the proportion of successful eCLIPs Device implants

at the target aneurysm.

2. Efficacy End Point: complete or near complete (Raymond 1 and

2) at 6 months and 12 months

3. Degree of Flow Diversion (reduction of blood flow into aneurysm)

immediately after successful eCLIPs Device implant.

4. Success of adjuvant coiling into aneurysm after successful

eCLIPs Device implant

5. Change in Modified Rankin Score from Baseline to 1, 6, and 12

Month Follow-up

6. Occurrence of unplanned aneurysm re-treatment within 12

months (endovascular or surgical repair)

7. Assessment of Device Migration at 6 months and 12 months

8. Assessment of artery stenosis at the device location at 6 months

and 12 months

9. Assessment of artery patency at the target aneurysm at 6 months

and 12 months

Study description

Background summary

Few licensed devices are available in Europe for the endoluminal (within the lumen/artery) treatment of bifurcation intracranial aneurysms, all in early stages of clinical evaluation. Evasc Medical Systems Corp. has developed an endovascular device specifically intended for use in conjunction with coils for the treatment of intracranial aneurysms arising at bifurcations. The eCLIPsTM Products are designed to address an
unmet clinical need for the treatment of bifurcation aneurysms.
Sixty-four percent of all cerebral aneurysms occur at arterial bifurcations. There are few commercially available stents or endoluminal devices designed specifically to treat bifurcation aneurysms. Current options for the endovascular treatment of bifurcation aneurysms include (i) simple coiling (no stent) and balloon remodelling, (ii) the use of commercially available stents "off-label" to create a Y-stent in conjunction with coils, (iii)
placement of coil-retaining devices in parent artery (e.g. PulseRider, pCONus);

and (iv) insertion of intrasaccular devices (e.g. WEB, Luna).
All these techniques have drawbacks and point towards the need for a therapy specifically designed to help treat bifurcation
aneurysms. The inadequacy of current techniques are the reason why an improved method and device designed specifically for treating bifurcation aneurysms are needed

Study objective

To provide preliminary technical feasibility, safety and efficacy data for eCLIPs Family of products.

Study design

This study will be a multi-centre, open label, single-arm feasibility, safety and efficacy study of the eCLIPs Products in the management of bifurcated intracranial aneurysms (IA) at basilar tip and carotid terminus. Patients will have saccular intracranial
aneurysms that arise at or adjacent to a bifurcation, having a neck length of >= 4mm or have a dome:neck ratio <2. At the discretion of the operator, 2 eCLIPs devices may be implanted, with one anchor section in one limb, and the other anchor section in the other limb, resulting in a degree of overlap of the 2 leaf portions across the aneurysm neck.
Coil placement with intravascular stents is commonly performed when treating large or wide necked sidewall aneurysms. Before coiling, but after eCLIPs Device implantation, the degree of flow diversion from the aneurysm by the appropriately placed eCLIPs
Device will be assessed using the OKM scale.
The study duration shall be long enough to obtain information on the safety, efficacy and technical feasibility of using the eCLIPs Products but not so long as to place participants at unnecessary risk due to unnecessary procedures, and generally will follow *usual* clinical care practices. The patients will be followed with clinical assessments at pre-discharge and 30 days and clinical assessment and radiographic imaging (cerebral angiography, DSA) at 6 month and 12 month follow up.

Study burden and risks

The study is designed to minimize the potential risks and complications in the subjects.
As a device developed specifically for bifurcated
aneurysms, the eCLIPs System can provide benefits to the patient that outweigh the current product risks. Potential risks associated with the use of the eCLIPs Bifurcation Remodelling
System are outlined below; these risks are similar to the use of any endoluminal arterial implant. Participants participating in the proposed clinical study

will be
monitored closely for any adverse events. It is likely that early detection of symptoms will allow early and more effective treatment of such symptoms. Potential adverse events are similar for any interventional arterial implant procedure and include but may not be limited to the following:
*Musculoskeletal
* Back pain
* Increased back pain
* Bursitis
* Pain at device insertion site
*Nervous System
* Anxiety
* Blindness
* Change in mental status
* Coma
* Confusion
* Dizziness
* Fever
* Headache
* Loss of consciousness
* Sciatica
* Seizure
* Neurologic deficit
* Vision Impairment
*Cardiovascular
* Air Embolism
* Arrhythmia
* Short-term arrhythmia
* Other arrhythmia
* Arteriovenous fistula
* Cardiac arrest
* Hypertension
* Hypotension
* Arterial spasm
* Vasospasm
* Myocardial infarction
* Tissue embolism
* Thrombotic embolism
* Ischemia
* Arterial Dissection
* Hemorrhage or Hematoma at entry site
* Vessel occlusion
*Vessel perforation
*Neurovascular
* Hemorrhagic Stroke
* Transient ischemia attack (TIA)
* Blood loss requiring transfusion

* Blood loss not requiring transfusion
* Vascular injury
* Hematoma
* Soft tissue damage
* Thrombophlebitis
* Dissection of the parent artery
* Vascular injury groin, bleeding
* Vascular injury groin, vessel and nerve damage
* Hydrocephalus
* Implant related, stenosis
* Implant related, thrombosis
* Rupture of aneurysm sac
* Rupture of parent artery
* Stenosis of parent artery
* Peripheral Thromboembolism
* Retroperitoneal hematoma
* Subarachnoid hemorrhage
* Thromboembolism from implanted device
* Thrombosis of branch vessel
* Thrombosis of parent artery
* Aneurysm recanalization
* Aneurysm enlargement
* Detachment of implant component
* Device migration or misplacement
* Device embolization
* Device thrombosis or occlusion
* Device fracture
* Hydrocephalus
* Occlusion of non-study vessel
* Cerebral Ischemic Stroke or Ischemia
* Coil Migration
* Incomplete aneurysm occlusion
* Intracerebral/intracranial Hemorrhage
* Mass Effect
* Perforator occlusion
* Perforated aneurysm
* Seizure
*Stroke
* Neurological deficits
*Respiratory
* Pulmonary embolism
* Bronchospasm
* Aspiration
*Genitourinary/Gastrointestinal
* Dysuria
* Hematuria
* Bladder fistula

* Nausea
* Vomiting
* Renal failure
*Immune System
* Anesthesia reaction
* Anaphylaxis
* Medication reaction
* Allergic pyrexia
* Allergic reaction including, but not limited to, contrast, Nitinol metal, and medications
* Contrast reaction
* Radiation exposure reaction
* Metal reaction (cobalt, chromium, platinum, tungsten)
*Infection/Inflammation
* Complications/skin burns from fluoroscopy exposure
* Superficial wound infection
* Deep wound infection
* Osteomyelitis
* Urinary tract infection
* Pneumonia
* Sepsis
* Other infection
*Other
* Death
* Other
In summary, the benefits of eCLIPs use in the patient population to be included in this study
outweigh the risks

Contacts

Public
Evasc

West 8th Avenue 107-1099
Vancouver V6H 1C3
CA
Scientific
Evasc

West 8th Avenue 107-1099
Vancouver V6H 1C3
CA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patient whose age is greater than 18 years old
2. Patient with an unruptured or previously ruptured (at least 1 months from date of rupture and with partial occlusion of the dome of the aneurysm by endovascular techniques or by open neurosurgery, and in stable neurological condition*WFNS I and II with a good recovery to at least to mRS 0-2) saccular, intracranial aneurysm or recurrent aneurysm, which arises at a bifurcation of Basilar Tip or Carotid Terminus and has a neck length of > 4mm or dome:neck ratio <2.
3. Patient aneurysm arises at a bifurcation artery with at least one of the two branch artery vessels having a diameter between 1.5mm and 3.25mm
4. Patient understands the nature of the procedure and has the capacity to provide informed consent.
5. Patient is willing to have on-site 30- day, 6-month, and 12 month follow-up evaluations as per standard clinical practice.

Exclusion criteria

1. Patient who presents with an intracranial mass or currently undergoing radiation therapy for carcinoma of the head or neck region.
2. Major surgery within previous 30 days or planned in the next 120 days after enrolment.
3. Patient with an International Normalized Ratio (INR)>= 1.5.
4. Patient with serum creatinine level >=104 µmol/L (or 2.5mg/dL) at time of enrolment.
5. Patient with a platelet count *100x103 cells/mm3 or known platelet dysfunction at time of enrolment
6. Patient who has a known cardiac disorder, likely to be associated with cardio-embolic symptoms such as atrial fibrillation
7. Patient with any condition that, in the opinion of the treating physician, would place the participant at a high risk of embolic stroke or with any medical co-morbidity likely to affect

the outcome (e.g. pulmonary disease, uncontrolled diabetes, blood disorders).
8. Patient with known allergies to nickel-titanium metal
9. Patient with known allergies to aspirin, heparin, ticlopidine, clopidogrel, prasugrel or other anti-platelet or P2Y12 agents or to general anesthesia.
10. Subject has resistance to Prasugrel based on a validated platelet testing method (Verify Now, Multiplate or other).
11. Patient with a life threatening allergy to contrast (unless treatment for allergy is tolerated).
12. Patient with inappropriate anatomy as demonstrated by angiography due to severe intracranial vessel tortuosity or stenosis, or intracranial vasospasm not responsive to medical therapy.
13. Patient who is currently participating in another clinical research study involving an investigational product.
14. Patient who has had a previous intracranial procedure associated with the target aneurysm such that access and placement of an eCLIPS device would be compromised
15. Stenting, angioplasty, or endarterectomy of an extracranial (carotid or vertebral artery) or intracranial artery within 30 days prior to the treatment date.
16. More than one intracranial aneurysm that requires treatment within 12 months.
17. Asymptomatic extradural aneurysms requiring treatment.
18. Severe neurological deficit that renders the subject incapable of living independently.
19. Unstable neurological deficit (i.e. worsening or improvement of clinical condition in the last 30 days.
20. Dementia or psychiatric problem that prevents the subject from completing required follow up.
21. Subject had a subarachnoid haemorrhage within 6 months prior to enrolment date.
22. Subject has a non-treated arterio-venous malformation in the territory of the target aneurysm.
23. Subject has a need for long-term use of anticoagulants.
24. Patient who is unable to complete the required follow-up.
25. Inability to understand the study or history of non-compliance with medical advice.
26. Evidence of active infection at the time of treatment.
27. Patient who is pregnant or breastfeeding.
28. Patient who has participated in a drug study within the last 30 days.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	eCLIPS device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-02-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-08-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-07-2019
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	NL54979.091.15