A Feasibility Study of the Surpass Aneurysm-Embolization System in Intracranial Arteries.

Gepubliceerd: 13-10-2009 Laatst bijgewerkt: 13-12-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21636

Bron
NTR

Verkorte titel
SP-02

Aandoening

Intracranial aneurysm
Intracraniaal aneurysma

Ondersteuning

Primaire sponsor: Surpass Medical Ltd.
14 Mintz Street
Tel Aviv, Israel

Overige ondersteuning: Surpass Medical Ltd.
14 Mintz Street
Tel Aviv, Israel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Adverse Events: For all subjects enrolled into the study, the incidence of adverse events will be assessed during the procedure, immediately post-procedure and through discharge. For all subjects with a deployed
device, adverse events will be assessed during the procedure, immediately post-procedure, at discharge, at thirty days and six months;
2. Technical Feasibility: For all subjects with a deployed device, evaluation of percent occlusion will be assessed at six months after treatment. Successful device placement will be angiographically assessed immediately post-procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksopzet

Subjects will receive a follow-up evaluation at thirty days (+ two weeks) and at six months (+ four weeks) with a follow-up angiography at six months.

Onderzoeksproduct en/of interventie

Endovascular treatment: A technique has been developed, in which a self-expanding device (Surpass Aneurysm-Embolization System), is placed across the aneurysm neck. This device attempts to restore blood flow through the main artery and in addition, to cause the aneurysm to become occluded. The device is a metal mesh, tubular shaped braided device that is compressed and placed into a catheter that is “threaded” up into the blood vessel in the head and is placed across the neck of the aneurysm.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subject understands the nature of the procedure and provides written informed consent;

2. Subject is willing to return to the investigational site for the thirty day and six month follow-up evaluations;

3. Age 18 years to 80 years;

4. Subject with a non-ruptured saccular or fusiform intracranial aneurysm arising from a parent vessel with a diameter of > 2mm and < 6mm;

5. Subject with an aneurysm that cannot be treated or is difficult to be treated with current available surgical or endovascular techniques.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy and lactating women;

2. Participation in another investigational drug or device study that has not completed the

primary endpoint or that clinically interferes with the endpoints of this study;

3. Allergy or contraindication to aspirin, clopidogrel, heparin, local or general anesthesia;

4. History of life threatening allergy to contrast dye;

5. Major surgery within previous 30 days or planned in the next 90 days after enrollment date;

6. Dementia or psychiatric problem that prevents the patient from completing required follow up;

7. Co-morbid conditions that may limit survival to less than one year;

8. Subject with anatomy not appropriate for endovascular treatement due to severe intracranial vessel tortuosity or stenosis, or intracranial vasospasm not responsive to medical therapy;

9. Subject with an intracranial mass (tumor (except meningioma), abscess, or other infection), or is undergoing radiation therapy for carcinoma or sarcoma of the head or neck region;

10. Subject has a history of bleeding diathesis or coagulopathy, international normalized ratio (INR) greater than 1.5, or will refuse blood transfusions;

11. Subject has a serum creatinine level greater than 2.0 mg/dL (within 7 days of procedure) which the investigator determines restricts the use of contrast agents;

12. Subject has a previously implanted intracranial stent associated with the symptomatic distribution within the past 12 weeks prior to enrollment date;

13. Stenting, angioplasty, or endarterectomy of an extracranial (carotid or vertebral artery) or intracranial artery within 30 days prior to enrollment date;

14. Subject has a previously implanted carotid stent associated with the symptomatic distribution within the past 12 weeks prior to enrollment date;

15. Subject has uncontrolled atrial fibrillation or known cardiac disorders likely to be associated with cardioembolic symptoms;

16. Subject had a subarachnoid hemorrhage within 12 weeks prior to the enrollment date;

17. Subject with resistance to ASA and/or Clopidogrel;

18. Subject with two or more aneurysms in associated distribution - unless the device is used to treat both aneurysms;

19. Subject has a non-treated arteriovenous malformation (AVM) in the territory of the target aneurysm;

20. Target aneurysm is expected to require more than one device.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-10-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1937
NTR-old	NTR2054
Ander register	Surpass Medical : SP-02
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A