Carotid Artery ImPlant for Trapping UpstReam Emboli (CAPTURE) for Preventing Stroke in Atrial Fibrillation Patients

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To assess the safety, feasibility, and tolerability of the Vine* Embolic Protection System and implantation procedure in atrial fibrillation (AF) patients at high stroke risk who are unsuitable for oral anti-coagulants (OAC).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON48800

Source
ToetsingOnline

Brief title
CAPTURE

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
Artrial fibrilation - abnormal heart rhythm

Research involving
Human

Sponsors and support

Primary sponsor: Javelin Medical Ltd.
Source(s) of monetary or material Support: industry

Intervention

Keyword: Atrial Fibrilation, Carotid artery, carotid filter

Outcome measures

Primary outcome

-Primary Safety Endpoints

Incidence of device and/or procedure related Major Adverse Events (MAEs) within

30 days of the final index procedure.

MAEs are defined as:

* Death

* Major and minor strokes

* Major bleeding

* Common carotid artery (CCA) stenosis > 70%

* S-3 Implant migration

* CCA thrombus

* Any complications in the CCA requiring endovascular treatment or surgery

-Primary Feasibility Endpoints

Procedure success, defined as:

* Proper S-3 Implant position in each CCA within 30 days of the final index

procedure

Secondary outcome

-Secondary Safety Endpoints

- Incidence of device and/or procedure related MAEs within 3, 6, and 12

months of the final index procedure.

-Secondary Feasibility Endpoints

• Successful delivery and deployment of the Implant in the CCA, defined as

proper Implant position within 4 hours of implantation procedure at each CCA

• Proper Implant position in each CCA within 3, 6, and 12 months of the final

index procedure

-Secondary Tolerability Endpoints

- Patient*s comfort at Post-procedure visit (Up to 4 hours post implantation),

at discharge, and at each follow-up visit

Study description

Background summary

Atrial fibrillation (AF) is a type of irregular heartbeat. These irregular heartbeats can potentially lead to the formation of a clot, which can travel to your brain and cause a stroke. Anticoagulants can reduce the stroke risk in AF patients, but treatment with these drugs is associated with a risk in bleeding and a lot of patients are not able to take this type of drugs.

The purpose of this study is to investigate whether the Javelin system can be used in patients with AF who are not suitable for oral anti-coagulants and to see how safe the system is. This device has never been used in humans before. Doctors cannot use the device outside a clinical study yet. It has been previously tested in the laboratory and on animals.

The Javelin System comprises a Delivery Device and a filter (Butterfly Implant) placed in the artery (CCA) which supplies blood to the head and neck and as

such preventing stroke producing clots from reaching the brain*

Study objective

To assess the safety, feasibility, and tolerability of the Vine* Embolic Protection System and implantation procedure in atrial fibrillation (AF) patients at high stroke risk who are unsuitable for oral anti-coagulants (OAC).

Study design

Multicenter, prospective, non-randomized, open-label, first-in-human (FIH) study.

Intervention

The implantation procedure is performed under ultrasound (US) guidance by a single operator under
sterile conditions. The operator holds the US probe in one hand and the Delivery Device in
the other hand. Local anesthesia is recommended; general anesthesia may be considered at operator
discretion. The time required for deployment in each side of the neck is expected to be less than one
minute.
The Implant is deployed in the CCA through a 24G needle (0.4 mm inner diameter). The operator
pierces the CCA wall with the needle, deploys the Implant, and retracts the needle. The Implant
is automatically deployed from the needle upon operator command.
*

Study burden and risks

The following assessments done during the screening visit: blood drawing, carotid ultrasound imaging and transthoracic echocardiogram (TTE) would not be done during standard follow-up of AF. The implantation of the carotid filters has never been done in humans and is therefore not standard practice. Study participation requires FU visites during the 4 years following the procedure, which is more than standard AF treatment. During standard follow-up visits one would not undergo ultrasound carotid imaging or neurological assessments. This is only required for the purpose of this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Atrial fibrillation (AF)
2. CHA2DS2-VASc score >= 2
3. Age > 50
4. Unsuitable for oral anticoagulation therapy (OAC), defined as contraindicated for OAC,
patient refusing OAC, or physician is reluctant to prescribe OAC
5. Maximal (systolic) CCA diameter range: >= 4.8mm and <= 9.8mm
6. CCA accessibility: up to 60mm from skin to CCA center, safe approach
7. Patient is willing to provide informed consent
8. Patient is willing to complete all scheduled follow-up

Exclusion criteria

1. Evidence of carotid stenosis > 30% [CCA, internal carotid artery (ICA), or external carotid artery (ECA)]
2. Evidence of any atherosclerotic disease in CCA above the clavicles
3. Evidence of carotid dissection
4. Pre-existing stent(s) in CCA
5. Contraindicated or allergic to antiplatelet therapy, or any medication required during the study
6. Recent stroke, TIA, or myocardial infarction (MI) within two months prior to index procedure
7. Female who is pregnant or who is planning to become pregnant during the course of the study
8. Life expectancy of less than 1 year
9. Active systemic infection
10. Known sensitivity to nickel or titanium metals, or their alloys
11. Known hereditary or acquired coagulation disorders
12. Any planned surgical or endovascular procedure within 14 days prior to or 30 days after the index procedure
13. A co-morbid disease or condition that could confound the neurological and functional evaluations or compromise survival or ability to complete follow-up assessments
14. Current use or a recent history of illicit drug(s) use or alcohol abuse (defined as regular or daily consumption of more than four alcoholic drinks per day)
15. Active participation in another investigational drug or device treatment study
16. Any other condition that in the opinion of the investigator may adversely affect the safety of the subject or would limit the subject's ability to complete the study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2018
Enrollment:	2
Type:	Actual

Medical products/devices used

Generic name:	Implant
Registration:	No

Ethics review

Approved WMO Date:	28-09-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-06-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	27-01-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-07-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL61969.100.17