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

Published: 28-09-2017 Last updated: 13-04-2024

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 reviewApproved WMOStatusRecruitment stoppedHealth condition typeCardiac arrhythmiasStudy typeInterventional

## **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**

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- -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**

#### **Public**

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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

- 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