CALM-FIM_EUR - CONTROLLING AND LOWERING BLOOD PRESSURE WITH THE MOBIUSHD* - A PROSPECTIVE MULTICENTER SAFETY STUDY

Published: 07-05-2013
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To evaluate the safety and performance of the Mobius HD system in subjects with resistant hypertension.

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

Summary

ID

NL-OMON45177

Source
ToetsingOnline

Brief title
CALM-FIM_EUR

Condition

- Other condition

Synonym
Drug resistant high blood pressure, Refractory Hypertension

Health condition

Resistant Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Vascular Dynamics, Inc. Clinical Research
Source(s) of monetary or material Support: Vascular Dynamics;Inc.

Intervention

Keyword: Carotid, Hypertension, MobiusHD

Outcome measures

Primary outcome

Safety: Incidence of serious adverse events (SAEs) and unanticipated adverse

device effects (UADE) reported for the study population from implantation

through six (6) months of follow-up.

Secondary outcome

Performance: Decrease in office cuff blood pressure (BP)

Study description

Background summary

Normal or optimal blood pressure (BP) is defined as the level at which minimal vascular damage occurs. The Joint National Committee 7 (JNC 7) defines normal BP as a systolic BP (SBP) less than 120 mmHg and diastolic BP (DBP) less than 80 mmHg.1
Page - 14-20 in Clinical Protocol

Study objective

To evaluate the safety and performance of the Mobius HD system in subjects with resistant hypertension.

Study design

This is an open-label, controlled, multi-center, first-in-man clinical trial to be conducted inside the EU. Eligible subjects with stage II resistant hypertension currently being treated with a minimum of three (3) anti-hypertensive drugs, which consent to study participation will be assigned

to treatment with:
• Mobius HD system
Potential study participants will be consented and then screened at two (2) baseline visits beginning at least 30 days prior to the procedure for Mobius HD placement. Qualified patients will undergo placement of the Mobius HD under angiographic visualization, and will then be followed for 18 months.
Subjects will be enrolled in two (2) phases, as follows:
• Ten subjects will be implanted unilaterally and followed for seven (7) days
• Based on consensus following 7-day clinical outcome analysis by an independent Data Safety Monitoring Board (DSMB), 10 additional subjects will be enrolled and implanted bilaterally.

Intervention

Light sedation and pain control is recommended to allow for clinical neurological assessment as needed
Note: Diabetic subjects taking drugs containing metformin should be switched to insulin management the night before the implant procedure and not be restarted on metformin until 48 hours after the last injection of contrast dye.
Heparin is given during the angiogram and implantation procedures (100 I.U./kg). ACT and/or measurement of platelet function is recommended according to local carotid stent protocols.
A stable vascular access with a long sheath and a coaxial 6 Fr guiding catheter, which should be placed as distal as possible, are strongly recommended to provide adequate support to navigate the implant delivery catheter around vascular curves.
The implant delivery catheter is prepared and introduced over a 0.014* guidewire. The sinus is passed by the guidewire followed by the implant delivery catheter to select an appropriate implant size, select the size that is appropriate to the measurement made of the diameter of the carotid sinus.
Distal protection may be used at this point using any approved distal protection device. The protection device should be used if there is any evidence of plaque within the vasculature.
Precise placement of the implant within the sinus is required and should be controlled by road map or contrast injections. All tension and slack should be pulled out of the delivery catheter. Implant delivery is performed by very slow retraction of the catheter by sliding the control knob proximally. Movement of the catheter must be strictly avoided. Post procedure angiography should be performed to evaluate proper implant positioning, apposition, and restoration of the vessel lumen. Careful retrieval of the delivery catheter is necessary to avoid dislodging the implant. Completion angiograms should display the implanted site and the dependent territory in at least two orthogonal planes.
Refer to instructions for use (IFU) for detailed prep procedure and detailed sizing and placement of the device. (Appendix VIII of the clinical protocol)

Study burden and risks

The potential risks associated with this procedure are currently unknown, but the risks should be reasonably similar to the known risks of a similar procedure called carotid angioplasty.
LONG TERM FOLLOW-UP VISITS will be performed: 18, 24, 30, 36-month, 1,5 year, 2 year, 2,5 year, 3 year follow-up visits.
During the long term follow-up visits after the angiogram/implantation procedure, clinical assessment of the subject and evaluation of neurological symptoms will be performed by the study team. Office cuff blood pressure will be taken and assessment of the subject diary will be reviewed. The neurological examinations are classified by NIHSS. Assessment for any new or unresolved adverse events will be made and any changes in medication regimen will be recorded.

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

Baseline Screening Visit 1 - (Day 0 - 14) - Assessed on Day 14
1. Provided written informed consent;
2. >= 18 years of age and <= 80 years of age;
3. Office cuff SBP >= 160 mmHg measured per protocol instructions (Appendix IV) following at least one (1) month of maximally tolerated therapy with at least three (3) anti-hypertensive medications, of which at least one (1) must be a diuretic unless patient has history of intolerance, ineffectiveness or contraindications. Any combination medications will be counted per the active ingredient. (For example, Zestoretic (Lisinopril +HCTZ) equals two (2) anti-hypertensive medications);
4. Carotid duplex studies demonstrating no obstructive carotid disease or plaque
5. Renal artery imaging performed within the last 12 months showing no evidence of renal artery stenosis. Acceptable imaging modalities include renal duplex, magnetic resonance angiography, CT angiography, and selective or nonselective renal angiography depending on trial site diagnostic standards. In the absence of adequate imaging testing this inclusion criteria could also be met by obtaining a renal duplex prior to enrollment, or by performing nonselective renal angiography at the time of device implantation.
6. Compliant with medications (self-reported); and
7. For females (with child-bearing potential), a negative pregnancy test, and the use of a medically accepted method of birth control for the duration of the trial.;Baseline Screening Visit 2 - (Day 15 - 30) - Assessed on Day 30
1. No significant obstructive vascular disease or plaque on CTA or MRA of the aortic arch and great vessels;
2. Continued adherence to hypertension medications without anticipated changes; and
3. Continued office cuff SBP >= 160 mmHg despite at least one (1) month of maximally tolerated therapy with at least three (3) anti-hypertensive medications, of which at least one (1) must be a diuretic unless patient has history of intolerance, ineffectiveness or contraindications. Any combination medications will be counted per the active ingredient. (For example, Zestoretic (Lisinopril+HCTZ) equals two (2) anti-hypertensive medications).;Day of Procedure -
1. Continued adherence to hypertension medications without anticipated changes.

Exclusion criteria

Baseline Screening Visit 1 - (Day 0 - 14) - Assessed on Day 14
1.Known or clinically suspected baroreflex failure or autonomic neuropathy;
2.Hypertension secondary to an identifiable and treatable cause other than sleep apnea;
3.Arm circumference greater than 46cm and/or BMI >= 40;
4.Chronic atrial fibrillation or recurrent atrial fibrillation with episode within the last 12 months;
5.Vulnerable plaque or ulceration of any size in the carotid artery or aortic arch;
6.History of bleeding complications with dual anti-platelet therapy in the past or has known

uncorrectable bleeding diathesis;
7.Current use of additional anticoagulation therapy. (Examples include vitamin K antagonists like warfarin, direct thrombin inhibitors, direct factor Xa inhibitors, thrombin IIa inhibitors like apixaban, rivaroxaban, dabigatran and etexilate;
8.Peptic ulcer disease with documented active ulcer or bleeding within the last year.
9.History of allergy to contrast dye that cannot be managed medically;
10.History of orthostatic hypotension;
11.History of syncope within the last six (6) months;
12.History of myocardial infarction or unstable angina within the past three (3) months;
13.History of cerebral vascular accident (stroke or TIA) within the past year;
14.Severe chronic kidney disease (calculated GFR < 30 ml/min);
15.Prior surgery, radiation, or endovascular stent placement in either carotid region;
16.Clinically significant structural valvular cardiac disease;
17.Moderate to severe reactive airway disease, chronic obstructive pulmonary disease, or primary pulmonary hypertension;
18.Uncompensated congestive heart failure or known severe reduction in left ventricular function (EF < 30%);
19.Uncontrolled co-morbid medical condition that would adversely affect participation in the trial;
20.Non-controlled diabetes mellitus;
21.Active infection within the last month;
22.Co-morbid condition that reduces life expectancy to less than one (1) year;
23.Mental health issues that would prohibit the subject*s availability to meet the Protocol requirements;
24.Currently taking an imidazoline receptor agonist or central sympathetic treatment;
25.Enrolled in a concurrent clinical trial;
26.Unable or unwilling to fulfill the protocol follow-up requirements;
27.Subject is a prisoner or member of other protected population;
28.Planned surgery or other procedure within the next six (6) months; or
29.Deep venous thrombosis (DVT) within the last year or documented recurrent DVT.;Baseline Screening Visit 2 - (Day 15 - 30) - Assessed on Day 30
1.ICA lumen diameters < 5 mm or > 11.75 mm.
2.Carotid hypersensitivity detected by carotid massage or typical history, as described in the Protocol (Appendix V); or
3.Significant aortoiliac or common femoral artery disease that will prohibit safe femoral access
4. Mean 24-hour ambulatory blood pressure < 130/80 mmHg.;Day of Procedure - Angiographic
1. Evidence of plaque, ulceration or any stenosis by angiographic evaluation in orthogonal views of the carotid artery. Lumen diameters will be assessed to exclude subjects with ICA lumen diameters smaller than 5 mm or larger than 11.75 mm.
2. Any plaque or ulceration on the arch angiogram involving the aortic arch and/or the origin of the great vessels;
3. Inappropriate anatomy of the carotid bifurcation for deployment of the MobiusHD, including, but not limited to; tortuosity of the extracranial vessels and significant angulation of the common carotid artery bifurcation;
4. Type III arch or horizontal takeoff of the left carotid from the innominate and

calcification of the carotid bulb.

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):	02-07-2013
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	Mobius HD System
Registration:	No

Ethics review

Approved WMO

Date:	07-05-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	06-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	30-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	10-02-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	01-04-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	22-04-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	02-06-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	08-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	13-10-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	11-11-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	22-05-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-07-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2018
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	NL41545.100.12