Treatment of resistant hypertension using a radiofrequency percutaneous transluminal angioplasty Catheter (POST MARKET APPROVAL SURVEILLANCE STUDY)

Published: 10-10-2012
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Aim of the study is to study a new therapeutic option for the treatment of hypertension

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON39303

Source
ToetsingOnline

Brief title
Reduce-HTN

Condition

- Vascular hypertensive disorders

Synonym
Therapy resistant hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Vessix Vascular, Inc

Source(s) of monetary or material Support: Vessix Vascular Inc.

Intervention

Keyword: balloon catheter, Hypertension, percutaneous, radiofrequency

Outcome measures

Primary outcome

Primary endpoint: Efficacy Endpoint

1. Reduction of systolic and diastolic blood pressure at six (6) months as measured by office-based blood pressure assessment (seated) following therapeutic renal denervation compared to baseline according to a standardized procedure using a validated electronic device (Omron model HEM-705 CP which includes a printer attachment).

2. Reduction of systolic and diastolic blood pressure at six (6) months as measured by 24-hour ambulatory blood pressure monitoring following therapeutic renal denervation compared to baseline using a validated ABPM device.

Secondary outcome

Secondary endpoints: Safety

Acute safety of the renal denervation procedure assessed by:

1. Renal artery dissection or perforation during the procedure that requires stenting or surgery;

2. Renal artery infarction or embolus;

3. Cerebrovascular Accident (CVA) at time of procedure;

4. Myocardial infarction at time of procedure;

5. Sudden cardiac death at time of procedure.

Long-term outcomes to further assess device safety and renal function:

6. Renal stenosis requiring an intervention documented by angiography;

7. Absence of flow limiting stenosis in the renal artery at six (6) months

follow up time points

8. Chronic symptomatic orthostatic hypotension;

9. Hypertensive emergency necessitating hospital admission, unrelated to

medication and/or non-compliance during the follow up period (2 years);

10. Reduction in estimated glomerular filtration rate > 25% during the follow

up period (2 years);

Study description

Background summary

Hypertension and its related conditions, heart failure and chronic kidney disease, represent a significant and growing global health issue. The World Health Organization (WHO) reports that high blood pressure afflicts one billion people worldwide (1 in 3 adults in the developed world). The prevalence of high blood pressure increases with age, obesity and sedentary lifestyles. Since all three factors are on the rise worldwide, hypertension treatment represents a large and growing clinical concern. Normal blood pressure is presently defined as 115/75 mm Hg (measured in millimeters of mercury) where the first figure represents systolic BP (SBP) and the second diastolic (DBP). For patients receiving treatment for hypertension, the target of treatment is reducing blood pressure below 140/90mm Hg. Hyper-activation of the sympathetic nervous system, especially the renal sympathetic nerves, is a major contributor to the pathophysiology of hypertension.

Study objective

Aim of the study is to study a new therapeutic option for the treatment of hypertension

Study design

a non-randomized, international, multi-center, prospective, single cohort, post

market clinical follow up study.

Intervention

Patients will be treated by renal sympathetic nerve denervation using RF energy applied with a balloon catheter. The treatment takes 30-60 seconds (depending on the length of the renal artery) and will be applied in both renal arteries

Study burden and risks

With any interventional procedure, there are possible risks and complications. It is believed that the risks associated with the use of the V2 Catheter are similar to other angioplasty devices.

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. Subjects who have provided written informed consent;
2. Subjects who are * 18 years and * 75 years of age;
3. Subjects who have SBP & DBP * 160/90 mm Hg based on an average of three (3) office-based blood pressure readings (seated) measured according to protocol;
4. Subjects on a stable medication regimen with * 3 anti-hypertensive drugs (one should be a diuretic, unless subject has a documented intolerance to diuretics) at maximally tolerated doses and have had no changes to the medication regimen two (2) weeks prior to enrollment;
5. Subjects with a eGFR * 45 ml/min per 1.73m^2;
6. Subjects who are willing and able to comply with all study procedures.;Anatomical Inclusion Criteria:
1. Subjects, with or without an accessory renal artery, with a main renal artery diameter of * 3.5 mm and * 7.0 mm for each of their kidneys.
2. Subject with a main renal artery without significant stenosis (stenosis defined as < 30%).
3. Subjects with a renal artery length of * 15 mm.

Exclusion criteria

1. Subjects with secondary hypertension;
2. Subjects who are contraindicated for intravascular contrast material;
3. Subjects who are contraindicated for anticoagulation medications (heparin, aspirin, Angiomax, etc.), analgesic medications (morphine, fentanyl, etc.), anxiolytic medications (alprazolam, lorazepam, diazepam, etc.) or other medications required for an interventional procedure;
4. Subjects with known bleeding or hyper-coagulation disorders;
5. Subjects who have type 1 diabetes mellitus;
6. Subjects who have experienced a myocardial infarction, unstable angina pectoris, uncompensated heart failure, or a cerebrovascular accident within six (6) months prior to the screening visit, or have widespread atherosclerosis, with documented intravascular thrombosis or unstable plaques;
7. Subjects who have planned percutaneous vascular or surgical intervention for any reason within the next 6 months;
8. Subjects who have hemodynamically significant valvular heart disease for which reduction of blood pressure would be considered hazardous;
9. Subjects who have an implantable cardioverter defibrillator (ICD) or pacemaker or abnormal electrocardiogram at time of screening;
10. Subjects who have any serious medical condition, which in the opinion of the investigator, may adversely affect patient safety or the efficacy of the procedure in the study (i.e., patients with clinically significant peripheral vascular disease, abdominal aortic aneurysm, bleeding disorders);
11. Subjects who are pregnant, nursing or planning to become pregnant or who are currently taking estrogen or any estrogen-like compound (female participants of childbearing potential must have a negative serum or urine human chorionic gonadotropin (hCG) pregnancy test

prior to the procedure);
12. Subjects who have a known, unresolved history of drug use or alcohol abuse/dependency;
13. Subjects who are currently enrolled in any investigational study wherein patient participation has not been completed;
14. Subjects who, for any reason, may not be able to understand or comply with instructions;
;Anatomical Exclusion Criteria:
1. Subjects with only one kidney;
2. Subjects with prior renal denervation procedure;
3. Subjects with prior intervention to right or left renal artery;
4. Subjects with renal artery stenosis as defined by * 30% stenosis confirmed by angiography with two (2) orthogonal views with selective catheterization;
5. Subjects with iliac stenosis requiring intervention at time of procedure and/or within the next six (6) months;
6. Subjects with severe femoral, renal, iliac or aortic calcification that may cause a potential complication at the time of the procedure;
7. Subjects in which the physician is unable to cannulate the renal artery;
8. Subjects in which the physician is unable to access the femoral artery by percutaneous means.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Renal sympathetic nerve denervation using radiofrequency

	applied percutaneously through a translumin
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT01541865
CCMO	NL39063.018.12