Rapid Renal Sympathetic Denervation for Resistant Hypertension Using the OneShot* Ablation System.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON37812

Source
ToetsingOnline

Brief title
RAPID

Condition

- Cardiac disorders, signs and symptoms NEC
- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Maya Medical
Source(s) of monetary or material Support: Covidien

Intervention

Keyword: Renal denervation hypertension ablation

Outcome measures

Primary outcome

1. RDN Acute Safety, defined as overall rate of Serious Adverse Events (SAE*s)

and adverse device effects at discharge:

(a) SAE*s related to groin and vascular access complications, and

(b) SAE*s related to renal artery injury

2. RDN Chronic Safety, defined as the overall rate of Serious Adverse Events

and Adverse Device Effects at 6 months

3. RDN Effectiveness, defined as Office Systolic Blood Pressure (SBP) reduction

>10 mmHg at 6 months compared to baseline

Secondary outcome

1. Procedure time

2. Fluoroscopy time

3. Rate of Office SBP reduction >=10mmHg at 12, 24 and 36 months compared to

baseline.

Study description

Background summary

Renal Denervation (RDN) is an emerging therapy intended to induce blood pressure-lowering on the basis of the ablation of efferent sympathetic and sensory afferent fibers of the renal nerves. Catheter based RDN is performed by commercially available Ardian Symplicity System. This is a single electrode catheter that is used to create multiple discrete, intentionally spaced ablation lesions. The operator progressively delivers 4-6 radiofrequency (RF)

ablation treatment at points distributed circumferentially along the length of the renal artery (point-by-point ablation). The procedure therefore requires both 90° rotation and pull-back of the catheter between each treatment. Clinical studies have shown effectiveness and safety in patients with uncontrolled hypertension, but the procedure is complex, lengthy and operator dependent.

Study objective

The OneShotTM System procedure is designed to provide the anatomical and physiologic benefits of catheter-based RDN at lesser risk to the subject, due to a reduction of complexity of the procedure and design improvements intended to enhance repeatability and reproducibility.

To collect information on clinical outcomes and safety in patients requiring RDN for the treatment of resistant hypertension treated with the OneShotTM System.

Study design

Multi-center, prospective, non-randomized, single arm clinical trial with intra-patient comparisons.

Intervention

Placed percutaneously, the OneShotTM balloon catheter is advanced into the renal artery using a routine femoral approach in a cardiac catheterization laboratory setting. RF is applied with pre-programmed time and intensity in each of the renal arteries.

Study burden and risks

The OneShotTM Ablation System may involve other risks and side effects that are as yet unknown.
The possible risks for this procedure include:
• Injury to the blood vessels or the kidneys
• Bleeding or the development of blood clots.
• Aneurysm
• Vessel thrombosis
• Infection in the groin or infection of the blood.
• Blockage of blood supply to vital organs by the catheter.
• Vessel dissection
• Hemorrhage,
• Vessel spasm
• Pulmonary embolism ,
• Perforation of the renal artery by the catheter

• Heart rhythm disturbances, such as a slowed heart rate
• Perforation of the vessel
• Heart Attack
• Pseudoaneurysm
• Stroke
• Kidney damage
• Skin burn and pain
• Hematoma
• Death
• Low blood pressure
• Allergic reactions to x-ray dye, local anesthesia and medication required for sedation during the procedure

Based on various studies with a standard renal denervation system in approximately 350 patients the following complications were observed:

* damage to the blood vessels of the kidney in approximately 1% of patients
* blood clots leading to heart attack or stroke in 1-2%
* extended stay in hospital for 1-2% of patients
* pseudoaneurysm groin artery in approximately 2% of patients
* (temporarily) low blood pressure in 1-2% of patients
* urinary tract infection in 1-2% of the patients
* placement of a stent in 1-2% of patients
* arrhythmias during the procedure in 2-4%

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. Systolic blood pressure >= 160 mmHg despite treatment with a regimen of 3 or more anti-hypertensive medications taken at optimal dose amounts including a diuretic and that has been stable for two weeks prior to screening.
2. Age 18-85 years
3. Able to provide informed consent and comply with follow-up visits

Exclusion criteria

1. Diameter of left or right renal artery less then 4mm or greater then 7mm.
2. Length of treatable segment of renal artery less than 20mm.
3. Renal arterial abnormalities including severe renal artery stenosis, previous renal stenting or angioplasty.
4. End-stage renal disease requiring dialysis or renal transplant
5. eGFR < 45 mL/min per 1.73 m2
6. Type 1 diabetes mellitus
7. Myocardial infarction, unstable angina, or cerebrovascular events within 6 months prior to screening
8. Severe valvular heart disease for which reduction of blood pressure would be considered hazardous
9. Bleeding disorder or refusing blood transfusions
10. Pregnancy or breast feeding
11. Peripheral vascular disease precluding catheter insertion
12. Any serious medical condition, which in the opinion of the investigator, may adversely affect the safety or effectiveness of the participant or the study
13. Current enrollment in another investigational drug or device
Study

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):	29-10-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	OneShot Ablation systeem
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-04-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-07-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-09-2012
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	NL39366.060.12