Renal Denervation in Patients with Uncontrolled Hypertension SYMPLICITY® Flex

Published: 18-03-2010
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The aim of the study is to evaluate the safety of the Flex catheter and the effect of the renal denervation on blood pressure.

Ethical review	Not approved
Status	Will not start
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON35055

Source
ToetsingOnline

Brief title
Renal Denervation

Condition

- Nephropathies

Synonym
Chronic kidney disease (or) chronic renal disease, high blood pressure, Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Ardian, Inc.
Source(s) of monetary or material Support: Ardian;Inc.;Palo Alto;CA 94303 USA

Intervention

Keyword: Denervation, Hypertension, Kidneys

Outcome measures

Primary outcome

1. To demonstrate that renal denervation achieved via the delivery of RF energy

is safe, and not associated with clinically significant adverse events.

Secondary outcome

To document the physiologic effects of denervation in patients with refractory

hypertension.

To determine whether renal denervation contributes to hypertension control.

To determine whether renal denervation improves renal function

To determine whether renal denervation contributes to improvement of glucose

management in patients with abnormal baseline Hemoglobin A1c

To assess the performance of the Ardian Symplicity Catheter System

Study description

Background summary

A set of pre-clinical studies have shown that renal denervation will decrease blood pressure. The System delivers low-level radiofrequency energy through the wall of the renal artery to denervate the human kidney. The catheter is introduced using standard interventional technique via the femoral artery, and is positioned in the renal artery under fluoroscopic guidance.The treatment involves the delivery of relatively low-power and precisely focused RF bursts of approximately 8W (contrasted with cardiovascular RF devices that generally operate in excess of 30W) through the wall of the renal artery to disrupt the surrounding renal nerves lying in the adventitia.

Study objective

The aim of the study is to evaluate the safety of the Flex catheter and the effect of the renal denervation on blood pressure.

Study design

The study is a non-randomized, open-label post-market clinical follow-up study to collect additional data on the safety and physiologic response of renal denervation in patients with refractory hypertension. This study will enroll up to one-hundred (100) participants at up to ten (10) research sites.

Intervention

The treatment involves the delivery of relatively low-power and precisely focused RF bursts of approximately 8W (contrasted with cardiovascular RF devices that generally operate in excess of 30W) through the wall of the renal artery to disrupt the surrounding renal nerves lying in the adventitia.

Study burden and risks

Risks associated to the procedure is extensively discussed in section E9. The burden for the participants: The procedure will take about an hour. Then the patients will be asked to visit the hospital 3 days, 1, 3, 6, 12, 18, 24 and 36 months (these visits will be combined to their regular visits of our out-patient clinic).

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

. Individual has a systolic blood pressure higher than 160 mmHg (higher than 150 mmHg for type 2 diabetics). 2. Individual is adhering to a stable drug regimen including 3 or more antihypertensive medications (with no changes for a minimum of 2 weeks prior to enrollment) that is expected to be maintained for at least 6 months. 3. Individual is >=18 and <= 85 years of age.

Exclusion criteria

. Individual has anatomically abnormal renal artery (this is defined in detail in the study protocol on page 13). 2. Individual has an estimated glomerular filtration rate (eGFR) of < 45mL/min/1.73m2 3. Individual has type 1 diabetes mellitus. 4. Individual has experienced a myocardial infarction, unstable angina pectoris, or a cerebrovascular accident within 6 months from the screening visit, or has widespread atherosclerosis. 5. Individual has a scheduled or planned surgery or cardiovascular intervention in the next 6 months. 6. Individual has hemodynamically significant valvular heart disease. 7. Individual has an implantable cardioverter defibrillator (ICD) or pacemaker, or any other metallic implant which is not compatible with MRI. 8. Individual has any serious medical condition, which in the opinion of the investigator, may adversely affect the safety and/or effectiveness of the participant or the study. 9. Individual is pregnant, nursing or planning to be pregnant. 10. Individual has a known, unresolved history of drug use or alcohol dependency. 11. Individual is currently enrolled in another investigational drug or device trial.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Not approved

Date:	18-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL31384.041.10
Other	volgt nog