ConfidenHTTM system safety and performance of diagnostic electrical mapping of renal nerves in hypertensive patients and/or potential candidates for a renal sympathetic denervation (RDN) procedure

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

Summary

ID

NL-OMON43150

Source
ToetsingOnline

Brief title
ConfidenHT

Condition

- Other condition

Synonym
High blood pressure, hypertension

Health condition

Hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Pythagoras Medical Ltd.
Source(s) of monetary or material Support: Pythagoras Medical Ltd.

Intervention

Keyword: Hypertension, Renal angiography, Renal nerve mapping, Renal sympathetic denervation

Outcome measures

Primary outcome

The incidence of serious adverse events (system and/or procedure related

events).

Secondary outcome

Arterial blood pressure changes to renal nerve stimulation.

Study description

Background summary

Hypertension (high blood pressure) is an epidemic, affecting nearly a billion people worldwide. The current firstline therapy for hypertension involves change in lifestyle and various medications. However, 20-35% of the patients does not respond to this treatment and fail to reach target blood pressure values. Without effective treatment, the medical condition of these uncontrolled hypertensive patients deteriorates, hence necessitating secondline therapies, including renal sympathetic denervation (RDN) RDN is a new potential treatment option for patients with hypertension. With an ablation catheter some of the nerves located near the renal artery can be destroyed leading to a reduction in the activity of the nervous system that is responsible for the high blood pressure. However, while this therapy proved to be very safe, a significant proportion of the patients proved not to respond in terms of blood pressure lowering. An important reason for the failure of the

therapy is the fact that both the location and the activity of the nerves cannot be visualized with the currently available technology. The technology under evaluation allows mapping of the renal nerves for providing guidance that will allow the physician to performing a targeted RDN therapy that will potentially increase treatment efficacy.

Study objective

In this study the safety and performance of diagnostic electrical mapping of renal nerves by means of the ConfidenHt console and catheter is assessed in patients who are hypertensive and/or potential candidates for a renal sympathetic denervation (RDN) procedure.

Study design

This study is designed as a multi-center, prospective, open label, single arm safety study to evaluate the ConfidenHt system. It consists of a screening, an intervention and a follow up period.

Intervention

Through a puncture of the groin (under local anesthesia) a catheter is advanced towards the renal artery around which several nerves are located which play an important role in the control of blood pressure. The physician will aim to visualize (map) these nerves by means of the ConfidenHT system.

Study burden and risks

Only patients with an already planned diagnostic coronary angiography and/or a renal sympathetic denervation procedure will be considered potential candidates for the study. With both procedures there is a specific and small risk of complications. The additional risks due to participation in this study is therefore very small. For patients undergoing a coronary procedure an additional risk of damage to the renal artery exists (described in ±1:200 patients) The additional risk of nerve stimulation with the ConfidenHT system, which is the purpose of the trial, will be very small as no ablation will be performed for the purpose of the study.

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

- Signed written informed consent.
- Age >18 years and <75.
- Either:
o Hypertensive patients planned to undergo elective cardiac catheterization
o Potential candidates for renal sympathetic denervation
- Main renal artery with diameter * 4.0mm.
- Glomerular Filtration Rate (GFR) >45.
- A patient who is mentally competent with the ability to understand and comply with the requirements of the study.
- The patient agrees to attend all follow-up evaluations and is willing to complete required exams and tests.

Exclusion criteria

- Previous participation in another study with any investigational drug or device within the past 30 days.
- Relevant renal artery disease (% diameter stenosis>30%, aneurysm or fibromuscular dysplasia).

- Known secondary causes of hypertension.
- The patient has a life expectancy * 12 months.
- The patient has undergone prior renal denervation, renal stenting, and/or abdominal aortic stent grafts.
- The patient has chronic oxygen use other than nocturnal support for sleep apnea.
- The patient has type I diabetes mellitus.
- The patient has had a previous organ transplant or is awaiting a renal transplant.
- Active implantable medical device (e.g. ICD or CRT-D; neuromodulator/spinal stimulator; baroreflex stimulator).
- The patient has triple ipsilateral artery ostia.
- Moderate to severe valvular heart disease.
- The patient has other concomitant conditions that may adversely affect the patient or the study outcome.
- Female who is pregnant, nursing or planning to become pregnant.
- Documented contraindication or allergy to contrast medium not amenable to treatment.

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):	19-10-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	ConfidenHTTM System
Registration:	No

Ethics review

Approved WMO Date:	23-12-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT02777216
CCMO	NL58523.078.16