The Neo Non-Randomized Hypertension Study, a Study of Baroreflex Hypertension Therapie in Refractory Hypertension

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The purpose of this clinical investigation is to verify the efficacy and safety of the CVRx Neo Baroreflex Activation Therapy System in subjects who qualify for the implantation for a Baroreflex Activation Therapy System.

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

Summary

ID

NL-OMON38413

Source
ToetsingOnline

Brief title
Neo Non-Randomized Hypertension Study

Condition

- Vascular hypertensive disorders

Synonym
refractory high blood pressure, therapy-resistant hypertension

Research involving
Human

Sponsors and support

Primary sponsor: CVRx Inc

Source(s) of monetary or material Support: bedrijf: CVRx Inc

Intervention

Keyword: baroreflex, hypertension, new model electronic device, treatment resistance

Outcome measures

Primary outcome

To describe the reductions in office cuff systolic blood pressure through six months of Baroreflex Activation Therapy® with the Neo system, relative to the screening blood pressure measurements.

To describe the safety of Baroreflex Activation Therapy utilizing the Neo system in the treatment of hypertension by evaluating all adverse events and estimating the rate of all system and procedure related complications through the 6-month visit.

Secondary outcome

NVT

Study description

Background summary

Subjects with hypertension are at an increased risk of developing cardiovascular disease. Given the trend of significant morbidity and mortality associated with hypertension, the usual treatment goals are aggressive in terms of 'normalizing' blood pressure level. A substantial part of subjects treated for hypertension are unable to achieve this blood pressure level.
In response to the need for more effective treatments in subjects with resistent hypertension, an active implantable medical device based therapy, the Rheos System, has been developed to lower blood pressure. It works by electrical activation of the carotid sinus baroreflex, which increass efferent nerve traffic through the carotid sinus nerve to the medullary brain centers

that regulate autonomic tone and blood pressure.

In this trial a new model, the Neo System will be investigated on safety and efficacy. When it's safe and effective, patients will have many benefits: the device is much smaller, has a longer longevity and only one lead will be implanted, what shortens the time of operation.

Study objective

The purpose of this clinical investigation is to verify the efficacy and safety of the CVRx Neo Baroreflex Activation Therapy System in subjects who qualify for the implantation for a Baroreflex Activation Therapy System.

Study design

The Neo Non-Randomized Hypertension Study will be conducted as a non-randomized, open-label, verification study in patients diagnosed with drug resistant hypertension. Up to sixty subjects will be implanted at up to 15 clinical sites in Europe and Canada. Up to 100 subjects will be enrolled to account for screen failures. After the patient has been determined to meet the enrolment criteria, he/she will be implanted with the Neo System. Therapy will be programmed OFF for the first two weeks following the implant. Two weeks following device implantation, therapy will be turned ON. Study visits will occur at 1, 2, 3, 5, and 6 months post-activation, quarterly through 12 months, and semi-annually thereafter.

Intervention

The Neo System is implanted during an operation procedure, which takes place in an operating room under general or local anesthesia. The electrode is wrapped around the carotic sinus at one side of the neck. The battery is subcutaneously placed below the clavicle. The electrode lead is extended through subcutaneously tunnels from the carotic sinus incision to the battery. The mean produre time is 1 - 2 hours.

Study burden and risks

The total burden for each patient is 52 hours during 4 years. The risks associated with participation are relatively small, an are similar to related surgical procedures involving the neck. These may include infections, bleedings, tissue damages and the occurrence of TIA or stroke. Regular measures are taken during the implant procedure to decrease the risks of infection, bleeding and tissue damage. In case of a blood pressure reduction due to this therapy, long-term cardiovascular risks will decrease.

Contacts

Public
CVRx Inc

10900 73rd Avenue North Suite 116
Maple Grove, MN 55369
US
Scientific
CVRx Inc

10900 73rd Avenue North Suite 116
Maple Grove, MN 55369
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age at least 21 years and no more than 80 years.
Office cuff systolic blood pressure (SBP) >= 140 mmHg
Normal anatomy of carotic artery bifurcations
An optimal stable anti-hypertensive therapy
not pregnant and contemplating pregnancy during study period
compliant on therapy

Exclusion criteria

known of suspected baroreflex failure or autonomic neuropathy
Body Mass Index above 45

Myocardial Infarction, unstable angina, syncope or CVA within the past 3 months
Carotic atherosclerosis producing a 50% or greater reduction in diameter
Prior surgery, radiation, or endovascular stent placement in the carotid sinus region
Hypertension secondary to an identifiable and treatable cause other than sleep apnoea.

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):	17-02-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Neo System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-02-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-03-2012

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-02-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL34630.068.10

Study results

Date completed:	29-08-2014
Actual enrolment:	9

Summary results
Trial is onging in other countries