ROX CONTROL HTN Study: A Prospective, Randomized, Open-Label, Multicenter Study to Evaluate the ROX Coupler in Patients with Resistant Hypertension

Published: 29-03-2013
Last updated: 26-04-2024

The objective of this study is to evaluate the safety and performance of the ROX Coupler in subjects with resistant hypertension.

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

Summary

ID

NL-OMON39868

Source
ToetsingOnline

Brief title
ROX CONTROL HTN

Condition

- Vascular hypertensive disorders

Synonym
High Blood Pressure ; Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Clinical Department
Source(s) of monetary or material Support: Sponsor - ROX Medical Inc.

Intervention

Keyword: Medical Device, Resistant Hypertension

Outcome measures

Primary outcome

Primary Endpoints:

- Change in 24-hour ABPM mean systolic blood pressure (SBP) at six

months as compared to baseline

- Change in mean office SBP at six months as compared to baseline

Secondary outcome

Secondary Endpoints:

- Change in 24-hour ABPM mean diastolic blood pressure (DBP) at six

months as compared to baseline

- Change in mean office DBP at six months as compared to baseline

- Change in mean home SBP and DBP at six months as compared to baseline

- Incidence of complications directly associated with delivery and/or

use of the ROX Coupler

Study description

Background summary

Hypertension is a disease that affects more than 76 million adults in the United States >= 20 years of age1 and approximately one billion individuals worldwide. According to a 2011 report from the American Heart Association

(AHA) based on NHANES/NCHS data through 2008, one in three adults has high blood pressure, and 71% of these subjects were undergoing treatment for hypertension. The AHA further reports that only 47.8% of patients had their hypertension under control and 52.2% did not have it controlled. A lowering of blood pressure by even modest amounts has the potential to substantially reduce morbidity and mortality. A meta-analysis of 61 prospective studies on one million adult patients indicated that a 10 mmHg reduction in systolic blood pressure lowered risk of stroke mortality by 40% and lowered risk of ischemic heart disease mortality by 30%. Furthermore, it is estimated that lowering diastolic blood pressure by 5 mmHg reduces the risk of stroke by 34% and reduces the risk of ischemic heart disease by 21%.

When hypertension becomes severe and resistant to medication the patient is no longer able to maintain goal blood pressure, <140/90 mmHg. The prevalence of resistant hypertension is projected to increase due to the aging population, increasing trends in obesity, sleep apnea, and chronic kidney disease. Resistant hypertension is associated with significant cardiovascular disease and patients have an increased risk of stroke, dissecting aortic aneurysm, myocardial infarction, congestive heart failure and renal failure compared to other hypertensive patients. In many cases, no clinically meaningful decrease in blood pressure is obtained despite adherence to a recommended treatment plan. Alternative therapies, such as the ROX Coupler, may address the significant unmet clinical needs of patients with resistant hypertension who are unable to control their blood pressure using standard medical treatment.

Study objective

The objective of this study is to evaluate the safety and performance of the ROX Coupler in subjects with resistant hypertension.

Study design

This is a prospective, randomized, open-label, multicenter study to evaluate the safety and performance of the ROX Coupler in patients with resistant hypertension. Safety and performance of the ROX Coupler will be evaluated in up to 100 subjects at up to 15 study sites. Patients with documented resistant hypertension who are interested in participating in the study will provide informed consent prior to baseline to determine eligibility. Baseline tests should be performed within 45 days prior to Day 0. Eligible patients will be enrolled in the study and these patients will be randomized in a 1:1 ratio to Treatment Group A (ROX Coupler implantation + continuing standard antihypertensive medication as prescribed by physician) or Control Group B (continuing standard antihypertensive medications as prescribed by physician). Randomization will be stratified by study site and previous treatment with renal denervation. Patients will return for clinical examination at 1 month, 3

month, 6 months, 9 months and 12 months. At 24 and 36 months, the subjects will be contacted via telephone to assess for home blood pressure and adverse events. At 6 months, for patients randomized to Control Group B, study physicians will discuss with patients the possibility to cross-over to Treatment Group A, if they still meet the protocol eligibility criteria.

Study burden and risks

Risks of the right heart catheterization and/or placement of the ROX Coupler include, but are not limited to, pain relating to the procedure, swelling in the leg, bleeding or bruising around the insertion site, blood infections, damage to your blood vessels, or changes in heart function.

The ROX Coupler may cause swelling in the leg because the vein, close to where the ROX coupler has been positioned, has narrowed. This narrowed vein could increase the risk of blood clots.

See Protocol Section 6.1.4 for Anticipated Adverse Events and Appendix IV for definitions of

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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. Office Systolic blood pressure >= 140 mmHg based on an average of 3 blood pressure readings;2. Ambulatory Blood Pressure Monitoring (ABPM) daytime average:
• Systolic blood pressure (SBP) >= 135 mmHg;
AND
• Diastolic blood pressure (DBP) >= 85 mmHg ;See Protocol Section 4.4.1 for complete Inclusion Criteria

Exclusion criteria

1. Secondary hypertension attributable to a cause other than sleep apnea
2. Type I diabetes
See Protocol Section 4.4.2 for complete Exclusion Criteria

Study design

Design

Study phase:	3
Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2012

Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	ROX Coupler
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-03-2013
Application type:	First submission
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
Other	01642498
CCMO	NL41910.100.12