Endovascular Renal Sympathetic Denervation using the Boston Scientific Vessix V2 renal denervation system to Improve Heart Failure

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Primary objective: To assess the safety and efficacy of endovascular renal nerve ablation using the Boston Scientific Vessix V2 renal denervation system in patients with systolic heart failure

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON40689

Source
ToetsingOnline

Brief title
IMPROVE-HF-I

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Boston Scientific,Research grant vanuit Boston Scientific

Intervention

Keyword: mIBG, Renal denervation, Systolic heart failure, Vessix V2 system

Outcome measures

Primary outcome

Difference in iodine 123 meta-iobenzylguanidine (123I-mIBG) late heart to

mediastinum ratio at 6 months.

Secondary outcome

Primary safety endpoint

The occurrence of a combined endpoint of cardiovascular death,

rehospitalization for heart failure, and acute kidney injury at 6 months.

Other study parameters (if applicable, APPENDIX IV for definitions)

Secondary safety endpoints (at 1, 3 and 6 months and yearly up to 5 years):

• Major access site bleeding

• Individual parameters of the combined endpoint

• Change in renal function (eGFR, Cystatine C)

• Development of end stage renal failure

• Newly acquired renal artery stenosis and/or repeat renal artery intervention.

Secondary efficacy endpoints (at 1, 3 and 6 months and yearly up to 5 years):

• NYHA class baseline and follow-up

• Body weight reduction

• 6 minute walk test

• Change in diuretic dosage

• Difference in 24-hour urine sodium excretion

• Quality of life and overall physical and mental function (using RAND 36-

item health survey [RAND-36] and the Kansas City Cardiomyopathy questionnaire).

• Change in heart failure and diabetic medication

• Echocardiographic endpoints (ejection fraction, wall thickness, dimensions,

diastolic function, pulse wave velocity) (at baseline, 6 months and yearly up

to 5y)

• Blood and urine analyses (change in NT-proBNP and catecholamine levels, renal

function, liver function, blood count, cholesterol levels, glycemic control)

(at baseline, 3 months, 6 months and yearly up to 5y)

Study description

Background summary

Chronic heart failure ìs a global and growing health problem. Despite gradual improvements in medical and device therapy, patients remain symptomatic and the prognosis remains poor. Sympathetic overactivity has been documented in heart failure with the severity of overactivity directly correlated to NYHA heart failure class.
Endovascular renal nerve ablation has been introduced as a promising new treatment modality to decrease sympathetic activity. Recently two small pilot studies demonstrated the potential benefit of renal nerve ablation in systolic heart failure. Currently no prospective randomized data is available on the safety and efficacy of renal denervation in improving signs and symptoms of heart failure.

Study objective

Primary objective: To assess the safety and efficacy of endovascular renal nerve ablation using the Boston Scientific Vessix V2 renal denervation system in patients with systolic heart failure

Study design

A prospective randomized controlled trial that will allocate 70 patients to treatment with renal nerve ablation or optimal medical therapy alone (1:1). Patients will be followed for 5 years and will be assessed at 1, 3, 6 and 12 months, and yearly up to 5y.

Intervention

The renal sympathetic denervation procedure will be started with gaining femoral artery access, either left of right, using a standard endovascular Seldinger technique to canulate the femoral artery. Placed percutaneously, the Vessix renal denervation catheter will be advanced into the renal artery. Radiofrequency ablation will be applied by using an automated programmed algorhythm.

Study burden and risks

Patients will undergo thorough pre-procedure assessment and imaging assessment (both MRI ultrasound) prior to selection and inclusion into the study. The procedure is initiated by puncture of the femoral artery with its inherent risks including bleeding, aneurysm formation, dissection, thrombosis and perforation. However, these risks are not different from each comparable form of angiography in which the groin is punctured and the access procedure is known for its low and acceptable complication risk. An additional potential procedure risk is caused by the radiofrequency ablation of the renal artery with focal damage of the endothelium on the coagulation spots. However, study data thus far do not show any signs of arterial damage due to the ablation procedure.

Based on previous studies using the Simplicity renal denervation system in approximately 350 patient, the following complications were recorded:
- damage to the blood vessels of the kidney in approximately 1% of the patients
- blood clots leading to heart attach or stroke in approximately 1-2%
- extended hospital stay in 1-2%
- pseudoaneurysm of the femoral artery in approximately 1-2% of the patients
- (temporarily) low blood pressure in 1-2% of the patients
- urinary tract infection in 1-2% of the patients
- renal artery stening in 1-2% of the patients
- arrhythmias during the procedure in 1-2%

In the recently presented interim data of the Vessix REDUCE-HTN trial, no

patient experienced prespecified acute safety events (n=146). A low rate of procedure-related adverse events was noted (5.5%; including hematoma (1), bilateral flank pain (1), vomiting (1), access site infection (2), pseudoaneurysm at access site (1), femoral artery thrombus (1), renal artery stenosis requiring treatment (1)).

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. Age >=18 years;
2. Systolic ejection fraction (established on echo) <35%;
3. NYHA Class II, III or IV heart failure despite optimal heart failure therapy;
4. Renal arteries suitable for the proposed treatment;
5. A glomerular filtration rate of 30ml/min/1.73m2 or more;

6. Written informed consent;
7. The patient agrees to the follow-up.

Exclusion criteria

1. Pregnancy;
2. Renal artery abnormalities;
3. Acute heart failure;
4. A systolic office based blood pressure of <110mmHg systolic;
5. Recent (<3months) stroke or myocardial infarction
6. Hypertrophic obstructive cardiomyopathy, constrictive pericarditis
7. The patient has other medical illness (i.e., cancer) that may cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with limited life expectancy (i.e., less than one year);

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2014
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Vessix V2 Renal Denervation System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-04-2014
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
CCMO	NL47953.078.14