Renal artery nerve interruption guided by location and electrical stimulation

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23038

Source
NTR

Brief title
VOLT

Health condition

Essential hypertension

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: VU medical center
St Jude Medical

Intervention

Outcome measures

Primary outcome

- to study blood pressure changes in response to electrical stimulation pre- and post-ablation

Secondary outcome

- to study the effect of renal denervation on renal blood flow as expressed by renal flow reserve and resistance index.
- to study the effect of renal denervation on office- and ambulatory blood pressure.

- to study the effect of renal denervation on the efferent sympathetic nervous system activity as expressed by catecholamine levels and natriuresis.

- to study the effect of RDN on central sympathetic nervous activity as expressed by heart rate variability and peripheral arterial tonometry.

Study description

Study objective

The evidence for renal sympathetic denervation (RDN) in hypertensive patients is conflicting. Symplicity HTN-3, the only sham controlled study, proved negative although a modest overall effect of RDN is suggested. Today, no marker or functional test to guide RDN nor to establish a sufficient RDN procedure exists.

Recently, two intriguing observations have been accomplished. First, the distribution of renal sympathetic nerves in man has been studied, providing an anatomic map for denervation. Second, renal nerve stimulation (RNS) showed to induce a blood pressure increase in a human hypertension. The RNS-evoked increase was significantly blunted after RDN, thus providing an electrical map for denervation. Therefore it is hypothesized that anatomical and electrical stimulation guided and monitored renal denervation is superior compared to conventional renal denervation with respect to blood pressure reduction.

Study design

all experiments will be performed during the index procedure and 3 months after (expect for renal denervation)

Intervention

- renal nerve stimulation

- renal denervation

- hyperemic pressure and flow measurements

Contacts

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Eligibility criteria

Inclusion criteria

- Essential hypertension

- Three antihypertensive drugs, of which one a diuretic

Exclusion criteria

- Age > 65 y

- Ambulantory blood pressure > 180/110 mmHg in the absence of antihypertensive medication

- Renal clearance < 60 ml/min (MDRD)

- Secundairy hypertension

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-06-2016
Enrollment:	20
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46881
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5683
NTR-old	NTR5827

Register	ID
CCMO	NL56394.029.16
OMON	NL-OMON46881

Study results