# Feasibility of electrical mapping and stimulation of renal arteries in patients undergoing renal denervation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

# **Summary**

### ID

NL-OMON28437

**Source** Nationaal Trial Register

Brief title Renal Nerves Stimulation (RNS) Study

#### **Health condition**

Patients with refractory hypertension and patients with combined hypertension and paroxysmal or persistent atrial fibrillation.

Patients who are accepted for renal denervation or combined pulmonary vein isolation and renal denervation according to routine clinical practice are eligible for this study.

Patiënten met refractaire hypertensie en patiënten met gecombineerde hypertensie en paroxysmale of aanhoudende atrim fibrileren.

Patiënten die worden geaccepteerd voor renale denervatie of gecombineerde longaderisolatie met renale denervatie volgens routine klinische praktijk en in aanmerking komen voor deze studie.

## **Sponsors and support**

Primary sponsor: Department of Cardiology, Isala Source(s) of monetary or material Support: Sponsor

### Intervention

### **Outcome measures**

#### **Primary outcome**

Main study parameter will be the arterial blood pressure response to renal nerve stimulation (RNS) prior to renal denervation (RDN) and absence of blood pressure rise in response to pacing in the renal artery after renal denervation (RDN).

#### Secondary outcome

Blood pressure at 3, 6, 12 months after the intervention, and change in blood pressure compared to measurement before the intervention

# **Study description**

#### **Background summary**

Study design: Investigator initiated, single centre, feasibility study

Main objectives are twofold:

1. To investigate the feasibility of RNS in patients with therapy resistant hypertension, which is assessing the functional distribution of renal nerves using 3D imaging and differential pacing modalities.

2. To investigate the blood pressure responses and cardiac excitable properties to RNS, and subsequently perform a RDN procedure, guided by 3D mapping by two different techniques e.g. RNS-checked RDN and RNS-guided RDN procedures. Study population: 40 patients (18 - 80 yr old)

#### **Study objective**

We hypothesize that identification and localization of the sympathetic nerve bundles using 3D navigation systems and selective pacing manoeuvres will allow a functional approach to denervate the kidneys and improve the success rate of this procedure in patients with hypertension.

- We hypothesize that the renal nerve stimulation (RNS)-guided renal denervation (RDN) procedure will show better blood pressure data during follow up, since the completeness has been assessed in contrast to the RNS-checked RDN procedure.

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#### Study design

3,6,12 months outcome

#### Intervention

-RNS-checked RDN

- RNS-guided RDN

# Contacts

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# **Eligibility criteria**

## **Inclusion criteria**

- Patients with refractory hypertension and patients with combined hypertension and paroxysmal or persistent atrial fibrillation.

- Age 18-80 years
- Glomerularfiltrationrate >45 mL/min
- No history of renal artery stenosis

# **Exclusion criteria**

- Type 1 diabetes mellitus
- Contraindication to chronic anticoagulation therapy or heparin.
- Primary pulmonary hypertension.
- Known secondary cause of hypertension
- Renal artery stenosis >50% of the arterial lumen, or renal artery lumen ;Ü3 mm.
- Dual or triple ipsilateral renal artery ostia.

# Study design

#### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

# Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	40
Туре:	Anticipated

### **IPD** sharing statement

Plan to share IPD: Undecided

# Plan description

Not decided yet

# **Ethics review**

Positive opinion Date: Application type:

23-01-2014 First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

ID: 41331 Bron: ToetsingOnline Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL4239
NTR-old	NTR4384
ССМО	NL47172.075.13
OMON	NL-OMON41331

# **Study results**

Summary results N/A