# Renal Nerves Stimulation Study

Published: 10-02-2014
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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...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON41331

**Source**
ToetsingOnline

**Brief title**
RNS

### Condition

- Other condition
- Vascular hypertensive disorders

**Synonym**
high blood pressure, hypertension

**Health condition**

central autonomic nervous system

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken
**Source(s) of monetary or material Support:** industrie

## Intervention

**Keyword:** 3D imaging, renal denervation ablation, renal nerve stimulation

## Outcome measures

### Primary outcome

Arterial blood pressure response to RNS prior to RDN and absence of blood

pressure rise in response to pacing in the renal artery after 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

Approximately 10-15% of adults with hypertension are considered to be treatment resistant because their hypertension is uncontrolled despite taking three or more drugs that includes a diuretic. Renal denervation (RDN) is a novel treatment option for therapy resistant hypertension and its rationale originates in denervating the renal sympathetic efferent and afferent coupling with the central autonomic nervous system. By denervating the renal arteries, general sympathetic tone is reduced.
Currently, renal denervation is performed by placing in a spiral pattern 5-6 ablation lesions in each renal artery. 15-30% of the patients do not have any benefit from this procedure. The reason for this is unknown.

### Study objective

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.

Secondary objective:

The secondary objective is to compare both techniques (RNS-checked vs. RNS-guided) in terms of efficacy and safety.

### Study design

Investigator initiated, single centre, prospective, feasibility study

### Study burden and risks

A total number of 40 patients will be included. Twenty patients will be treated with the RNS-checked RDN procedure and 20 patients will be treated with the RNS-guided RDN procedure.

Based on clinical experience, we expect that 40 patients will be sufficient to provide data on the abovementioned aims and endpoints.

## 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

Patients with refractory hypertension
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 <=3 mm
Dual or triple ipsilateral renal artery ostia

## Study design

### Design

| | |
|---|---|
| Study phase: | 2 |
| Study type: | Observational invasive |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-03-2014 |
| Enrollment: | 40 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 13-02-2014 |
| Application type: | First submission |
| Review commission: | METC Isala Klinieken (Zwolle) |
| Approved WMO Date: | 23-02-2016 |
| Application type: | Amendment |
| Review commission: | METC Isala Klinieken (Zwolle) |
| Approved WMO Date: | 16-08-2016 |
| Application type: | Amendment |
| Review commission: | METC Isala Klinieken (Zwolle) |

# Study registrations

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

No registrations found.

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

ID: 28437
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| ClinicalTrials.gov | NCT02496117 |
| CCMO | NL47172.075.13 |
| OMON | NL-OMON28437 |