Treatment of atrial fibrillation in patients with high sympathetic activity by pulmonary vein isolation in combination with renal denervation or pulmonary vein isolation only; an international randomized, controlled trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47122

Source
ToetsingOnline

Brief title
ASAF trial

Condition

- Other condition
- Cardiac arrhythmias

Synonym
Atrial fibrillation, hypertension

Health condition

Hypertensie en signalen van sympathische overactiviteit

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atrial fibrillation, Hypertension, Pulmonary vein isolation, Renal denervation

Outcome measures

Primary outcome

Time to first detection of atrial fibrillation >30 seconds, with the monitoring

period starting 3 months after the intervention.

Secondary outcome

- AF burden after 12 months of follow-up, expressed in % of the monitoring

period, in patients with continuous rhythm monitoring. The monitoring period

starts 3 months after the intervention.

- Blood pressure at 3, 6, 12 months after the intervention, and change in blood

pressure compared to measurement before the intervention

- Blood pressure and heart rate response changes induced by exercise testing

- Changes in heart rate variability measures tested by Holter monitoring

compared to measurement before the intervention

- Changes in arterial stiffness measures post intervention AASI (ambulatory

arterial stiffness index) by ambulatory blood pressure monitoring, PWV (pulse

wave velocity) and augmentation index compared to measurement before the

intervention

Study description

Background summary

Atrial fibrillation (AF) is the most common arrhythmia and is poorly controlled by medication. Ablation therapy (pulmonary vein isolation; PVI) is a class I indication in AF resistant to medication. In most patients sympathetic overdrive is a provocative factor inducing AF episodes. Hypertension is very common in these patients.

Renal denervation (RDN) is a new therapy 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.
Hypertension is very common in patients with AF. Furthermore, a rise in sympathetic adrenergic tone can induce AF. We hypothesize that RDN in combination with PVI will improve the success of ablative therapy. If our study provides evidence for the effectiveness of RDN in combination with PVI, Medtronic*s RDN devices could be widely used in patients with AF, undergoing ablative therapy.

Study objective

Primary objective is twofold:
- To investigate if RDN in combination with PVI prevents AF in patients with AF and with out of range hypertension (systolic >140 mmHg or >130/80 mmHg in diabetics and patients with chronic renal disease) or signs of sympathetic overdrive.
- To investigate if RDN in combination with PVI is more successful in achieving long term sinus rhythm than PVI alone, in patients with AF and out of range hypertension or signs of sympathetic overdrive.

Secondary objective(s): To investigate the effects of RDN in combination with PVI on:
• the general sympathetic drive of the body
• the blood pressure
• the diurnal blood pressure profile
• markers of arterial function and arterial stiffness

Study design

Prospective, randomized, controlled, multicenter, international clinical trial

Intervention

The study population consists of patients with paroxysmal or persistent AF with out of range hypertension or signs of sympathetic overdrive. Patients will be randomized into two groups:
Group 1: RDN + PVI
Group 2: PVI

Study burden and risks

RDN and PVI are established as safe therapies for therapy resistant hypertension and symptomatic atrial fibrillation respectively. Success rates are 80% for RDN in combination with PVI as treatment of therapy resistant hypertension and 60% for PVI alone as treatment of AF. The complication risk is <4% for PVI and is <1% for RDN.

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

The patient falls within the target group resistent hypertension or sympathic overdrive
Patient is an acceptable candidate for renal denervation treatment
Patient is < 75 year of age

Exclusion criteria

Contraindication to chronic anticoagulation therapy or heparin
Previous left heart ablation procedure for AF
Acute coronary syndrome, cardiac surgery, PCI or stroke within 3 months prior to enrolment
Renal artery stenosis >50% of the arterial lumen, or renal artery lumen <=3 mm

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	04-11-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-02-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-07-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-01-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-08-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	18-06-2018
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02115100
CCMO	NL45174.075.13