Standard re-ablation versus advanced HD mapping guided ablation in recurrent symptomatic atrial fibrillation or atrial tachycardia after initial pulmonary vein isolation

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To determine the clinical effectiveness of HD mapping guided tailored ablation as compared to standard re-ablation that targets PV reconnection and antral tissue only in patients with symptomatic AF or AT requiring re-ablation after initial PVI.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON49664

Source
ToetsingOnline

Brief title
HD REDO-AF

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation or atrial tachycardia after initial pulmonal vein isolation. Irregular heart rate

Research involving
Human

Sponsors and support

Primary sponsor: Maatschap Cardiologie Zwolle
Source(s) of monetary or material Support: Maatschap Cardiologie Zwolle

Intervention

Keyword: Atrial fibrillation, Atrial tachycardia, Pulmonal Vein Isolation, Redo ablation

Outcome measures

Primary outcome

Successful therapy defined as freedom from AF and AT, beyond three months of blanking period during 12 months follow up without class I or III AAD.

Secondary outcome

To determine whether HD mapping guided antral re-ablation of the PVs and additional tailored ablation improves AF related and general QoL as compared to standard re-ablation that targets PV reconnection and antral tissue only in patients with symptomatic AF requiring re-ablation after initial PVI during 6, 12 and 24 months follow up.

To determine from the viewpoint of society whether HD mapping guided ablation as compared to standard re-ablation that targets PV reconnection and antral tissue only in patients with symptomatic AF requiring re-ablation after initial failed PVI can be preferred in terms of costs, effects and utilities.

Study description

Background summary

Pulmonary vein isolation is the cornerstone, and the only proven effective

invasive treatment method of atrial fibrillation in the absence of overt underlying heart disease. Unfortunately 20-40% of the ablated patients experience recurrent arrhythmia and a repeat procedure is generally considered. Reconnection of one or more pulmonary veins is a common finding in these cases, however, comparable rate of reconnection has also been demonstrated in patients without arrhythmia recurrence. Furthermore, repeat ablation of these reconnections does not eliminate the symptoms in all patients suggesting the role of extrapulmonary triggers and substrate. In specific subset of patients several studies have shown increased success rate of ablation when non-PV triggers or left atrial low voltage area*s where involved in the ablation procedure, however, there is still a need for solid evidence in patients with recurrent atrial fibrillation and atrial tachycardia after initial pulmonary vein isolation.

Study objective

To determine the clinical effectiveness of HD mapping guided tailored ablation as compared to standard re-ablation that targets PV reconnection and antral tissue only in patients with symptomatic AF or AT requiring re-ablation after initial PVI.

Study design

This is a prospective randomized, controlled, two arm, multicenter, double blind clinical study conducted in the Netherlands. Patients will be randomized in a 1:1 ratio to receive either limited or extensive ablation as described above.

Intervention

The standaard re-ablation approach involves antral re-isolation of the pulmonary vein without any additional ablation.

The HD mapping guided ablation involves detailed LA voltage mapping in SR and/or AF. In all patients antral re-isolation of the PVs will be performed. In patients with a normal LA voltage and non-inducibility of AT/AFL/AF with pacing and isoproterenol challenge: no further ablation. In patients with inducible AT/AFL/AF: targeted ablation of documented or induced macro re-entrant atrial tachycardia*s, ablation of focal ectopic atrial tachycardia*s, ablation of reproducible non- PV triggers as described by Natale et al. and cavotricuspid isthmus ablation in patients with typical AFL ablation, ablation or isolation of left atrial low voltage areas.

In order to blind clinicians performing follow up, details about the performed ablation will be noted exclusively in the ECRF.

Study burden and risks

No extra risks or benefits.
The risks of the ablation therapy are the same as routine treatment.
The difference is that not the investigator but the randomization determined the treatment.

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

- Previous PVI without any further ablation lesions other than cavo-tricuspid isthmus line due to atrial fibrillation.
- Clinical indication for redo ablation due to documented symptomatic atrial

fibrillation or atrial tachycardia lasting longer than 30 seconds
- Age 18 years or older
- Able and willing to comply with pre- and follow up testing and requirements
- Patient is willing and capable to provide written informed consent

Exclusion criteria

- LAVI > 60 ml/m2
- AF secondary to electrolyte imbalance, thyroid disease, or reversible or uncontrolled non-cardiac cause
- Contraindication to anticoagulation therapy (i.e. Heparin, NOAC*s or acenocoumarol)
- Life expectancy less than 12 months
- Presence of intramural thrombus, tumor or other abnormality that precludes catheter ablation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	238
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-08-2020
Application type:	First submission
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
CCMO	NL66889.075.18