Magnetic Resonance Imaging for lesion visualization after catheter ablation for treatment of atrial fibrillation

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Evaluate and quantify whether lesion formation can be visualized using MRI in subjects undergoing a catheter ablation for paroxysmal atrial fibrillation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON54655

Source
ToetsingOnline

Brief title
MRI for lesion visualization after catheter ablation

Condition

- Cardiac arrhythmias

Synonym
paroxysmal atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: verzekeraars

Intervention

Keyword: arrhythmia, atrial fibrillation, catheter ablation, MRI

Outcome measures

Primary outcome

Main study parameters: visualization and quantification of atrial edema and

scar after catheter ablation at different time points using CMR.

Secondary outcome

Secondary study parameters: oesophagus damage, left atrial volume index (LAVI),

left atrial wall thickness, diameter pulmonary veins, pre-existent scar tissue,

MRI thrombus detection (CT and TOE redundancy), atrial function pre- and

post-ablation.

Study description

Background summary

Catheter ablation for atrial fibrillation (AF) has become a first-line therapy, whereas pulmonary vein antrum isolation (PVAI) is still widely accepted as the cornerstone of ablation therapy in all types of AF. Unfortunately, due to insufficient lesion creation many patients require subsequent catheter ablation (CA) procedures to treat AF recurrence due to electrical reconnections between left antrum (LA) and pulmonary veins (PV). Visualization of lesion creation by the use of cardiac MRI (CMR) might improve clinical outcomes and reduce the need for additional CA procedures. In this pilot study, we will evaluate lesion visualization at different points in time for both edema and scar tissue evolution for the purpose of determining the optimal time points for lesion visualization in the acute phase (edema) and in the later phase (scar).

Study objective

Evaluate and quantify whether lesion formation can be visualized using MRI in subjects undergoing a catheter ablation for paroxysmal atrial fibrillation.

Study design

Monocenter, investigator-initiated, prospective, explorative, observational, longitudinal study.

Study burden and risks

Four MRI exams in a fixed time schedule will be performed:
- 1) MRI prior to ablation (within 1 week prior to ablation),
- 2) MRI directly after ablation (<1 hour post-ablation),
- 3) One of the following time points: 3a) MRI 24 hours post-ablation, 3b) MRI one week post-ablation, 3c) MRI one month post-ablation
- 4) MRI three months post-ablation

Although MRI is a non-invasive diagnostic imaging technique it can be associated with nau-sea, headache and general discomfort, especially in subjects suffering from claustrophobia. The subject risks associated with the additional MRIs are neglectable. The potential burden is in the associated time of the additional MRIs and the associated gadolinium containing con-trast agents. However, we will minimize this burden by planning most of the MRIs during hos-pitalization or regular hospital visits. In every patient the MRI exam is performed at time-point 1), 2) and 4). Although anesthesia used for catheter ablation is prolonged for the 2) MRI, this decreases the burden of the experience of MRI for the subject.

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

- 18 years of older
- Diagnosed with paroxysmal atrial fibrillation
- Planned to undergo catheter ablation
- Written informed consent present

Exclusion criteria

- Unable to provide informed consent
- Contraindications for a diagnostic cardiac MRI (unstable implants, implanted devices <30 days, neuro clips, allergy to gadolinium contrast medium, renal impairment (eGFR < 30mL/min/1.73 m2)
- Contraindications for catheter ablation (documented intracardial thrombus, tumour, bleeding, coagulation or other abnormality which limits catheter ablation)
- Myocardial infarction, of a maximum of 60 days prior to inclusion
- Instable angina pectoris
- History of cerebrovascular event
- Clinically significant structural heart disease (this includes: tricuspid valve insufficiency or stenosis and other congenital heart diseases) which limit the insertion of the catheter, as determined by the physician
- Uncompensated chronic heart failure
- The arrhythmia is secondary to an electrolyte disbalance, thyroid disease, or any other reversible non-cardiac cause
- Known sensitivity for heparin or warfarin
- Active or systemic infection
- Any other significant non-controllable or instable medical condition
- Pregnancy
- Life expectancy of less than 12 months
- Subjects with prosthetic valves
- Subjects of 75 years of age or older
- Weight of more than 200 kilos

- Patients with inadequate anticoagulation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2021
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO

Date:	17-11-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-02-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	11-10-2023

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL70037.058.19