CMR characterization of ablation lesions following pulmonary vein isolation.

Published: 18-03-2021
Last updated: 08-04-2024

Using state of the art CMR imaging techniques, we will characterize ablation lesions in the early phase after pulmonary vein isolation, and relate findings to (1) the ablation scar at 3 months follow up and (2) atrial fibrillation-free survival at 1...

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

Summary

ID

NL-OMON52010

Source
ToetsingOnline

Brief title
CMR characterization of ablation lesions

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ablation, Atrial fibrillation, Cardiac magnetic resonance imaging, Pulmonary vein isolation

Outcome measures

Primary outcome

The relation between ablation lesion characteristics in the early phase after

pulmonary vein isolation and (1) ablation scar at 3 months follow-up, and (2)

atrial fibrillation-free survival at 1 year.

Secondary outcome

N.a.

Study description

Background summary

Pulmonary vein isolation is the cornerstone of ablation therapy in patients with atrial fibrillation. Index-guided radiofrequency ablation is a safe technique for this purpose. However, the efficacy is limited by a high rate of atrial fibrillation recurrence within the first year after pulmonary vein isolation (20-50%).
Previous imaging and histopathological studies showed that ablation can result in both permanent and reversible tissue injury (incomplete ablation), which may explain the high recurrence rate of atrial fibrillation after pulmonary vein isolation, due to pulmonary vein reconnection. Early identification of incomplete ablation, suitable for additional ablation, is important to improve pulmonary vein isolation techniques, leading to less redo procedures, and may further pave the way for real-time CMR guidance of pulmonary vein isolation procedures.

Study objective

Using state of the art CMR imaging techniques, we will characterize ablation lesions in the early phase after pulmonary vein isolation, and relate findings to (1) the ablation scar at 3 months follow up and (2) atrial fibrillation-free survival at 1 year.

Study design

Single center observational study.

Study burden and risks

All patients will receive standard medical care for pulmonary vein isolation, including visits to the outpatient clinic and ambulatory monitoring. Additional CMR using a contrast agent will be performed within 72 hours after pulmonary vein isolation (preferable at the day of discharge) and at 3 months follow-up to characterize the ablation lesions, which will take 60 minutes. The additional risks associated with participation are minimal. Gadolinium is a safe contrast agent, which is frequently used in clinical practice. Intravenous gadolinium administration may cause minimal injection site reactions (e.g. pain, cold or burning sensation). As with other contrast-agents, anaphylactic-like reactions can occur, although this is very unusual. For safety reasons a medical doctor will be present during the scanning sessions to monitor the patient*s status. Patients with a known (suspected) allergic reaction to gadolinium or severe kidney failure (GFR <45 ml/min/kg) will be excluded. The results of the present study will be used for optimizing pulmonary vein isolation techniques and may further pave the way for real-time CMR guidance of pulmonary vein isolation procedures.

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

Adult patients (age >=18 years old)
Paroxysmal or persistent atrial fibrillation meeting guideline criteria.
Anticipated pulonary vain isololation using index guided radiofrequency ablation techniques.
Availability of contrast-enhanced cardiac MRI within 3 months before anticipated pulmonary vein isolation.

Exclusion criteria

History of catheter ablation
History of cardiac surgery
History of chest radiation therapy
Known (or suspected) allergic reaction to gadolinium
Estimated glomerular filtration rate (eGFR) <45 ml/min/kg
Contraindications for CMR
Inability to schedule CMR <72h after PVI
Long-term use of anti-inflammatory medication, except for the use of nonsteroidal anti-inflammatory drugs
Autoimmune disease or chronic inflammatory illness.
Pregnancy of breast feeding

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):	01-09-2022
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Cardiac Magnetic Resonance Imaging
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL75456.029.20