

Impact of catheter ablation of atrial fibrillation on the left atrium

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To determine the impact of catheter ablation on the left atrium by visualizing scar tissue in the left atrium, using delayed enhancement MRI, and to correlate this to possible changes in left atrial size and function following catheter ablation.

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

Summary

ID

NL-OMON33017

Source

ToetsingOnline

Brief title

Impact of catheter ablation on the left atrium

Condition

- Cardiac arrhythmias

Synonym

atrial fibrillation

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atrial fibrillation, cardiac imaging, catheter ablation, scar tissue

Outcome measures

Primary outcome

The primary study parameters are scar tissue in the left atrium and left atrial size and function.

Secondary outcome

The secondary study parameters include age, gender, type of atrial fibrillation, duration of atrial fibrillation, the presence of structural heart disease and hypertension.

Study description

Background summary

Catheter ablation has proven to be an effective treatment of atrial fibrillation. However, its impact on the left atrium is unknown. Scar tissue in the left atrium, induced by the ablation procedure, may have an impact on left atrial function which may have consequences for the medical treatment after catheter ablation. If left atrial function is impaired after catheter ablation, patients should receive anticoagulation in order to prevent thromboembolic events.

Study objective

To determine the impact of catheter ablation on the left atrium by visualizing scar tissue in the left atrium, using delayed enhancement MRI, and to correlate this to possible changes in left atrial size and function following catheter ablation.

Study design

This observational study will include patients with atrial fibrillation who will be admitted for catheter ablation. Prior to and a few months after catheter ablation, patients will undergo a cardiac MRI scan with additional

delayed enhancement imaging. After the conventional scan, patients will have to wait for approximately 15 minutes while they are lying on the MRI table. Afterwards, a second series of images will be obtained to depict scar tissue in the left atrium which takes 5 minutes. Administration of an extra dose of contrast agent will not be necessary. The obtained images will be used to measure the extent of scar tissue in the left atrium before and after catheter ablation and this will be correlated to the observed changes in left atrial size and function. After catheter ablation, patients will be regularly seen at the outpatient clinic to determine the rhythm status of the patients. Participation in this study will have no further consequences regarding treatment strategy or follow-up.

Study burden and risks

Participation in this study will not result in serious adverse events. Expected minor adverse events may result from inconvenience due to a longer imaging time, for example back pain or claustrophobia. Termination of the imaging procedure will take place if these adverse events occur.

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

- symptomatic, drug refractory AF
- age \geq 18 years
- catheter ablation will be performed
- a minimum follow-up duration of 4 months

Exclusion criteria

- participation in another research

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-11-2009

Enrollment: 50

Type: Actual

Ethics review

Approved WMO

Date:	22-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL26887.041.09