Efficacy of DE-MRI-Guided Ablation vs. Conventional Catheter Ablation of Atrial Fibrillation

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To examine the efficacy of targeting atrial fibrotic tissue during an ablation procedure in treating persistent AF.We will also examine the efficacy of the fibrosis-guided ablation on a number of secondary or exploratory outcomes including the...

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

Summary

ID

NL-OMON53352

Source
ToetsingOnline

Brief title
DECAAF II

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, palpitations

Research involving
Human

Sponsors and support

Primary sponsor: University of Utah health Sciences Center
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ablation, atrial fibrillation, cardiac arrhythmias

Outcome measures

Primary outcome

To examine the efficacy of targeting atrial fibrosis tissue during an ablation procedure in treating persistent AF.

The frequencies and proportions of patients experiencing each of three components of the primary AA outcome:

atrial fibrillation

atrial flutter

atrial tachycardia

Secondary outcome

Quality of life as measured by the Toronto Score.

A composite outcome including AA recurrence and prescription of an anti-arrhythmic medication, stroke, cardiovascular hospitalization, a repeat ablation, AA recurrence following repeat ablation

Study description

Background summary

There is a strong association between AF and atrial tissue ;fibrosis. Recently, a novel DE-MRI (Delayed-Enhancement MRI) based imaging modality has been demonstrated to reveal the degree of fibrotic atrial tissue in patients suffering from AF. When applied in various studies, including a multi-center study, extent of fibrotic atrial changes was shown to be the strongest independent predictor of a successful treatment in patients undergoing ablation

of AF. Moreover, in the multi-center observational study DE-MRI Determinant of Successful Radiofrequency Catheter Ablation of Atrial Fibrillation (DECAAF), the strongest independent predictor of successful outcome was the surface area of fibrosis covered by ablation lesions. In fact, the number of encircled pulmonary veins, the most common adopted approach to ablate AF today, did not predict catheter ablation success.

Results from the DECAAF study show that one of the most important predictors of ablation outcome was the degree of ablation of the fibrotic tissue; the more fibrotic tissue that was overlapped with scar during ablation, the better the outcome. These results were the impetus for the primary objective of DECAAF II. Patients will be randomized to receive conventional pulmonary vein isolation (PVI) ablation or PVI + fibirosis-guided ablation. We will follow patients longitudinally to assess recurrence of persistent atrial arrhythmias (AA) (atrial fibrillation, atrial flutter or atrial tachycardia as defined by recent AHA/ACC/HRS guidelines2). We hypothesize that patients receiving brosis-guided ablation in addition to conventional PVI ablation will have fewer AA recurrences than those who receive PVI ablation alone.
This proposal is aiming at modifying and improving persistent AF management guidelines by evaluating targeting DE-MRI detected atrial fibrosis during AF ablation and its related effect on procedural outcome.

Study objective

To examine the efficacy of targeting atrial fibrotic tissue during an ablation procedure in treating persistent AF.
We will also examine the efficacy of the fibrosis-guided ablation on a number of secondary or exploratory outcomes including the individual components of the primary endpoint (recurrence of atrial fibrillation, atrial flutter and atrial tachycardia), symptomatic atrial arrhythmia, AF cycle length/regularity/termination, cardiovascular (CV)-related hospitalization, CV-related mortality, quality of life measurements (University of Toronto Atrial Fibrillation Severity Scale (AFSS), and AF burden.

The safety of the two interventions will be evaluated by evaluating peri-procedural complications including stroke, pulmonary venous stenosis, bleeding, esophageal injury,cardiac perforation, heart failure, and death.

Study design

DECAAF II is a prospective, randomized, multi-center trial of patients with persistent AF and presence of atrial fibrosis.
After consenting to participate in the study, the subject will undergo a DE-MRI scan to assess for extent of atrial fibrosis. After verifying adequate quality of the DE-MRI study, subjects will be randomized to one of two study groups to receive conventional PVI ablation (Group 1) or PVI + fibrosis-guided ablation

(Group 2). In Group 1, PVI ablation will be performed as recommended by the HRS consensus statement2 and physicians will be blinded to the pre-ablation MRI fibrosis results. In Group 2, physicians will receive the DE-MRI scan prior to the ablation procedure, will complete conventional PV isolation, and will also target left atrial fibrosis detected by MRI.

This is an event-driven trial, in which patient enrollment and follow-up will continue until approximately 517 randomized subjects experience the primary endpoint of AA recurrence. Under the assumptions described in Section 6 on page 29, it is anticipated that 888 subjects will be randomized, including 444 assigned to Group 1 and 444 assigned to Group 2. The actual number enrolled and the duration of the follow-up period will be adjusted as necessary to achieve the 517 required events.

Intervention

After verifying adequate quality of the DE-MRI study, subjects will be randomized to one of two study groups to receive conventional PVI ablation (Group 1) or PVI + fibrosis-guided ablation (Group 2)

Study burden and risks

There are potential risks related to the fibrosis-guided ablation procedures. Due to the longer time under anesthesia, more areas being ablated and longer total procedure time, subjects in the fibrosis-guided ablation group are at greater potential risk for scarring, injury to peri-esophageal vagal nerves, esophageal injury, cardiac perforation, and atrial esophageal fistulas. this risk is offset in part by the potential benefit from fibrosis-guided ablation, which may provide better clinical outcomes.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with persistent AF undergoing first AF ablation as per recent HRS consensus document. Persistent AF is defined by 7 days or more in AF as evidenced by either 1) rhythm strip or 2) written documentation.
- Must have some proportion of atrial fibrosis (not limited to advanced stage fibrosis).
- Able to understand and willing to sign the Informed Consent Form.
- Age * 18 years.

Exclusion criteria

- Contraindication for DE-MRI with a full dose of Gadolinium-based contrast agent.
- Previous left atrial ablation or surgical procedure.
- Women currently pregnant.
- Mental or physical inability to take part in the study.
- Uncontrolled hypertension.
- Inability to be placed in MRI due to body mass.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-01-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	22-10-2019
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
ClinicalTrials.gov	NCT02529319
CCMO	NL55002.098.15