An MRI-validated study of the superiority of a contact feedback catheter in AF ablation - pre study

Published: 03-02-2014
Last updated: 22-04-2024

To perform a pre-study to assess the feasibility of DE-MRI to assess lesion size, transmurality and completeness of pulmonary vein isolation. The study will be performed to determine if and how DE-MRI can be used in a larger subsequent multicentre...

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

Summary

ID

NL-OMON40242

Source
ToetsingOnline

Brief title
MERCI-AF pre study

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Directe financiering door CardioResearch Enschede

Intervention

Keyword: Atrial fibrillation, Contact, MRI, Pulmonary Vein Isolation

Outcome measures

Primary outcome

To perform a pre-study to assess the feasibility of DE-MRI to assess lesion size, transmurality and completeness of pulmonary vein isolation. The study will be performed to determine if and how DE-MRI can be used in a subsequent multicentre study (MERCI-AF study).

Secondary outcome

To collect data on the use of contact-feedback which could be included in the MERCI-AF study.

Study description

Background summary

Radiofrequency pulmonary vein isolation represents an established therapy for treating atrial fibrillation. The quality of catheter tip-to-tissue contact plays a critical role in ablation safety and efficacy. Catheters providing feedback on this tip-to-tissue contact have just become available. Effectiveness of radiofrequency ablation by these catheters has recently been demonstrated in humans.

Recently, DE-MRI has emerged as an effective method to noninvasively assess and quantify the extent of left atrial structural remodelling. The extent of LA fibrosis assessed by high-resolution DE-MRI has been introduced as an independent predictor of RF ablation failure. To demonstrate the superiority of using the contact catheters to conventional catheters for the effectiveness of AF ablation, post procedural MRI with delayed enhancement (DE-MRI) can possibly assess lesion size, transmurality of the lesion and completeness of pulmonary vein isolation and relate this to clinical outcome.

Study objective

To perform a pre-study to assess the feasibility of DE-MRI to assess lesion size, transmurality and completeness of pulmonary vein isolation. The study will be performed to determine if and how DE-MRI can be used in a larger subsequent multicentre trial (MERCI-AF study).

Study design

The study is designed as a feasibility study.

Intervention

Isolation of left or right sided (1:1 randomization) pulmonary veins with feedback on, the controlateral side is isolated using the same catheter but with feedback off.

Study burden and risks

Since in this study a procedure which is common clinical practice will be performed, there is no extra risk or burden associated with the intervention. The only part in the study differing from common clinical practice is the post-procedural MRI, the patient will not have to schedule an extra visit of the hospital since the visit will be combined with the common follow-up visit. The MRI will take about an hour.

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

• Paroxysmal atrial fibrillation for which >= 1 electrical and/or chemical cardioversions and persistent atrial fibrillation, eligible for pulmonary vein isolation according to current international guidelines.
• Age < 70 years.
• Willing and able to sign informed consent.
• Willing to and capable of following the requested study procedures.

Exclusion criteria

• Age < 18 years.
• Pregnancy
• Life or follow-up expectancy < 12 months.
• Previous pumonary vein isolation in history.
• Contrast allergy.
• Creatin clearance level lower than 60.
• MRI scanning not possible (e.g. because of metal implant or claustrophobia).
• Abnormal left atrium anatomy. This will lead to exclusion after inclusion but before andomisation.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Single blinded (masking used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	TactiCath Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-02-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
Other	In clinicaltrials.gov. Nog geen identificatienummer
CCMO	NL45733.044.13