Endocardial fractionation mapping in atrial fibrillation

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

Summary

ID

NL-OMON29711

Source
ToetsingOnline

Brief title
EndoMap_1

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Isala klinieken, lokatie de Weezenlanden
Source(s) of monetary or material Support: maatschap cardiologie van de Isala klinieken te Zwolle

Intervention

Keyword: ablation, atrial fibrillation, fractionation, mapping

Outcome measures

Primary outcome

1) Return of AF on routine holterscan, control surface ECG or holterscan or ECG

during complaints. Blinded period 0 to 3 months after ablation

2) Restart of anti arithmic drugs because of atrial arrhythmia, consisting of

AF, atrial flutter or atrial tachycardia.

Secondary outcome

na

Study description

Background summary

Catheter based ablation of atrial fibrillation (AF) has come of infancy since 1998. Currently the procedure is most often based on electrical isolation of the pulmonary veins alone or as part of an ablation also targeting the left atrial tissue surrounding the pulmonary veins and/or additional linear lines of ablation between right and left pulmonary veins and between the pulmonary veins and the mitral annulus. This is to prevent electrical impulses from within and around the pulmonary veins to trigger the onset of AF. The succesrate of this approach in paroxysmal AF is 70-90%. Normally the procedure is based on electrical isolation of the pulmonary veins to prevent triggers within the pulmonary veins to reach the atrial tissue and initiate AF. Recently a new approach is developed, targeting areas of atrial tissue showing fractionated electrical potentials. The new approach is based on the theory that the underlying slow conduction velocity and disturbed conduction patterns of these sites play an important role in the maintenance of AF. Preliminary data show this approach to be succesful in about 90% of patients.

Study objective

The objective of the current study proposal is to gain insight in the effect of pulmonary vein isolation on the electrophysiological properties nearby the

ablation lines on the posterior sight of the left atrium and further away, especially in the right atrium. The second objective is to gain more insight in the role of areas with abnormal conduction, evidenced by fractionated potentials, in the maintenance of AF. We will focus on the identification of predilection sites of fractionated potentials.

Study design

The design of the study is observational. We will include 30 patients with AF (paroxysmal or persistent). During the catheter based intervention we will record unipolar electrical signals to identify sites with abnormal conduction , as evidenced by fractionated potentials.

Study burden and risks

Nature and extent of the burden and risks associated with participation
We don*t anticipate an increase in periprocedural complications of the circumferential pulmonary vein isolation or accessory pathway ablation. However, the duration of the procedure will be lengthened by approximately 30 minutes, The follow up of the patients will be in accordance with usual care.

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 or persistent AF
Structurally normal heart
accepted for catheterablation of atrial fibrillation

Exclusion criteria

age >75 years or < 18 years.
Thyroid dysfunction
unable to give informed consent
critical illness

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-08-2006
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	18-07-2006
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL12629.075.06