Markers for Determining Atrial Remodeling in Patients with Atrial Fibrillation

Published: 21-11-2014
Last updated: 22-04-2024

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

Summary

ID

NL-OMON55444

Source
ToetsingOnline

Brief title
MARK AF

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation, heart rhythm disturbances

Research involving
Human

Sponsors and support

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

Intervention

Keyword: atrial fibrillation, atrial remodeling, biomarkers, invasive treatment

Outcome measures

Primary outcome

Changes in biomarkers involved in the remodelling process of the atrium in AF

will be related to the outcome after treatment.

Secondary outcome

NVT

Study description

Background summary

Atrial Fibrillation (AF) is the most common type of arrhythmia seen in clinical practice. Its prevalence is projected to grow at least two-fold by 2050, due to aging of the population. AF is a progressive disease and progression of the disease varies between patients. The pathophysiological process of AF is complex because of its multifactorial character. Increasing AF burden leads to structural and electrical remodeling of the atria, creating a substrate that is favourable for sustaining AF propagation, through electrical or structural remodeling. Specifically fibrosis is known to play an important role in the progression of the disease. However despite extensive research that has already been performed in the field of AF the exact pathophysiological process remains incompletely understood.
Minimally invasive treatment strategies for AF, using catheter ablation techniques or video-assisted thoracoscopic surgery , are promising, but success rates for these procedures are relatively low. Recognizing patients that are prone for recurrence of AF remains a challenge when determining a proper treatment strategy. The ability to identify subgroups of patients that can benefit from a specific treatment strategy might provide more individualized therapeutic opportunities, improve prognostication or provide preventive opportunities in patient with AF.

Study objective

The main objective of this study is to gain insight in the (reverse) remodeling process of the atria in patients with atrial fibrillation. T Analyses will be

conducted on the cardiac tissue and blood samples. We aim to correlate the findings from these analyses with clinical characteristics of patients with atrial fibrillation and to compare these findings with findings from analyses on atrial tissue, fat and blood from a control population. With these results we aim to identify both non-invasive and invasive diagnostic markers to determine the pathophysiological process of AF in individual patients

Study design

The study is a single center study.

Study burden and risks

The collection of blood poses no significant risk to the patients.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients with AF, undergoing VATS-PVI
- Age between 18 and 80 years
- Symptomatic AF, paroxysmal, persistent or longstanding persistent
- AF was documented on ECG/Holter/Pacemaker electrogram at least once in the 12 months preceding presentation

Exclusion criteria

- Left ventricular ejection fraction < 30%
- Severe heart failure (NYHA IV)
- Pregnancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2015
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	21-11-2014

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-08-2021
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	NL50069.018.14