The nECG system: Identification and quantification of atrial fibrillation and the patient burden in patients with paroxysmal atrial fibrillation undergoing catheter ablation

Published: 30-01-2014
Last updated: 23-04-2024

1. Primary objectiveThe identification and discrimination of AF burden and the patient burden of the nECG system in patients with paroxysmal AF undergoing catheter ablation for AF.2. Secondary objectiveAssess the relation between the changes in...

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

Summary

ID

NL-OMON40289

Source
ToetsingOnline

Brief title
Identification and quantification of paroxysmal AF after catheter ablation

Condition

- Cardiac arrhythmias

Synonym
Atrium fibrillation, heart rhythm disturbance

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AF, AF buren, biomarkers, monitoring

Outcome measures

Primary outcome

AF burden and the possibility of arrhythmia identification (AF, atrial flutter, atrial tachycardia) will be determined. Monitoring duration and patient compliance will be documented from the duration of the recordings and patient satisfaction will be measured using a questionnaire after the three week monitoring period. Finally, the changes in biomarkers involved in the reverse remodeling of the atrium in AF will be related to the burden of AF in the preceding monitoring periods.

Secondary outcome

na

Study description

Background summary

Extending the duration of ambulatory electrocardiographic monitoring can improve the detection of AF and may be useful in determining the burden of AF in patients before and after treatment. The burden of AF might influence underlying reverse remodelling processes involved in the pathophysiology of AF. Biomarkers are a representation of these processes and insight in these processes might guide clinical decision making. For monitoring an implantable loop recorder can be implanted under the skin on the chest and monitor the rhythm accurately for prolonged periods. However it is expensive and is a small surgical procedure with the chance of small procedural risks. Non invasive

continuous monitoring (Holter) or longer term intermittent monitoring (event or loop recorder) can be used as ambulatory monitoring devices. However, such technologies have generally been limited by patient compliance, the analyzable wear time and electrode skin irritation. Recently a novel wearable device for extended ambulatory ECG monitoring (nECG) became available that might increase patient compliance and accuracy of AF detection.

Study objective

1. Primary objective
The identification and discrimination of AF burden and the patient burden of the nECG system in patients with paroxysmal AF undergoing catheter ablation for AF.

2. Secondary objective
Assess the relation between the changes in biomarkers involved in the reverse remodeling of the atrium in AF and the burden of AF in the preceding monitoring period

Study design

This study is an observational two-center study.

Study burden and risks

The benefit of this study is that introduces a non-invasive comfortable wearable monitoring device to ascertain the occurrence of AF. The nECG is more comfortable and easier in use than a regular Holter. In addition it allows for a longer monitoring duration, to increase the capture of AF occurrence. For individual patients participating in the study, there is a higher chance of AF documentation, due to the prolonged monitoring period, preventing a possible repeat investigation to document AF. Therefore, the rhythm monitoring will consist of three weeks instead of two days. Additionally, a total of 20ml of extra blood will be sampled during routine blood tests investigation for additional analysis of biomarkers. There is no risk to the patient when participating in this study related to the nECG. There is a very limited chance of allergic skin reactions (atopic eczema), due to the use of gel or the detergent to wash the band. The monitoring device is safe and has received a CE mark.

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

Any patient with an indication for catheter ablation treatment of symptomatic paroxysmal AF can enter the study.;The patients should conform to the following criteria:
• Age between 18 and 80 years
• Paroxysmal AF, as defined following the ESC 2010 Guidelines.
• At least one class I or III anti-arrhythmic drug in standard dosage has failed or is not tolerated.
• Legally competent and willing to sing the informed consent.
• Willing and able to adhere to the follow up visit protocol.

Exclusion criteria

If any of the following criteria is present, patients cannot enter the study and will thus not be asked for written informed consent:
• Prior intervention (catheter ablation or minimally-invasive surgical ablation) for AF.
• AF secondary to electrolyte imbalance, thyroid disease or other reversible or non-cardiovascular causes.
• Active infection or sepsis (as evidenced by increased white blood cell count, elevated CRP

level or fever >38,5C)
• NYHA class IV heart failure symptoms or left ventricular ejection fraction <35%.
Cerebrovascular accident (defined as any sudden neurological deficit lasting longer than 24 hours, with or without pathological changes on the CT cerebrum) with the preceding 6 months
• Unable to undergo TEE
• Requirement of antiarrhythmic medication for ventricular arrhythmias
• Presence of intracardiac mass or thrombus (Discovery of any thrombus or intracardiac mass after signing of the informed consent will result in withdrawal of the patient from the study)
• Circumstances that prevent follow up.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2014
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Rhythm monitoring system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-01-2014
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2014
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	NL47181.018.13