BioMonitor III: Validation of the Atrial fibrillation Detecting algorithm in patients undergoing pulmonary vein isolation

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Evaluation of the AF detection performance of the BioMonitor III ICM in patients who are scheduled for a PVI in comparison to simultaneous Holter monitoring.

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

Summary

ID

NL-OMON48234

Source
ToetsingOnline

Brief title
BioVAD study

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation, irregular heart rhythm

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Biotronik

Intervention

Keyword: Atrial fibrillation, Implantable loop recorder, Pulmonary vein isolation

Outcome measures

Primary outcome

Primary endpoints are the sensitivity, specificity, positive predictive value

and negative predictive value of AF detection by the BioMonitor III in

comparison to Holter monitoring at the 2 timepoints (pre- and post PVI).

Secondary outcome

The secondary objective is to demonstrate the freedom from ICM- or

insertion-related complications at 6 months post-ICM insertion.

Study description

Background summary

Pulmonary vein isolation (PVI) is the cornerstone of interventional treatment of symptomatic atrial fibrillation (AF). Several methods are available to establish the efficacy of catheter ablation of AF. According to the 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of AF, the minimal monitoring recommendations for paroxysmal or persistent AF recurrence post-ablation does not include an ICM; however, in the setting of clinical trials, extended ECG monitoring is encouraged. The commercially available insertable cardiac monitors (ICMs) have different AF detection algorithms, but are largely based on R-R interval irregularity. Runs of ectopy with irregular coupling intervals, undersensing of beats, oversensing of myopotentials, or underlying sinus arrhythmia may be sources of false positive AF detection. The BioMonitor III is a new ICM with a long sensing vector with gives a better R-wave amplitude. Currently, there is no data on the AF-detection performance of the BioMonitor III ICM. The aim of the current study is to provide data on the AF performance of the BioMonitor III ICM specifically in patients who undergo PVI.

Study objective

Evaluation of the AF detection performance of the BioMonitor III ICM in

patients who are scheduled for a PVI in comparison to simultaneous Holter monitoring.

Study design

Single-center prospective observational study in which the AF detection performance of the BioMonitor III ICM will be investigated before and after PVI.

Study burden and risks

Implantation of an ICM is a relatively simple procedure with a low risk of periprocedural complications. The device is placed subcutaneously using local anesthetics. The most important complications are pocket infection and local hematoma, which are generally well manageable. The BioMonitor III is CE marked. Holter monitoring is a standard non-invasive diagnostic tool used in the outpatient clinic.

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

1. Diagnosis of paroxysmal or persistent AF as defined by the 2016 ESC guidelines for the management of atrial fibrillation
2. Subject scheduled to undergo PVI within 6 months
3. Subject willing and able to comply with the follow-up requirements of the study
4. Written informed consent obtained from subject aged 18 years or older

Exclusion criteria

1. Diagnosis of long-standing persistent AF as defined by the 2016 ESC guidelines for the management of atrial fibrillation
2. Subjects implanted with a previous ICM, pacemaker, ICD, or cardiac resynchronization therapy device
3. Subjects with an active infection
4. Subjects enrolled in another clinical study which may confound the results of this study
5. Subjects with a life expectancy of <1 year due to any condition

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	18-12-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23516
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70462.078.19
Other	NL7777
OMON	NL-OMON23516