# 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.

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON23516

**Bron**
NTR

**Verkorte titel**
BioVAD

**Aandoening**

Paroxysmal and persistent atrial fibrillation

### Ondersteuning

**Primaire sponsor:** Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
**Overige ondersteuning:** Biotronik SE & Co. KG

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

AF detection performance metrics of the BioMonitor III ICM device compared to that of simultaneous Holter monitoring in patients before and after PVI.
AF detection performance of the BioMonitor III ICM device will be expressed as sensitivity, specificity, positive predictive value and negative predictive value (both for episodes and duration).

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: The BioMonitor III is an insertable cardiac monitor (ICM) which is capable to automatically detect atrial fibrillation (AF). As ICMs are increasingly being used to detect AF recurrence after pulmonary vein isolation (PVI), data on the performance of the AF detection algorithm in this specific population is important.

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 population: Thirty adult patients with paroxysmal or persistent AF who are scheduled to undergo PVI.

Intervention: A BioMonitor III ICM will be implanted at study entry. At the 1-week post-insertion visit (scheduled in the 3 months prior to PVI), patients will receive a Holter for up to 4 consecutive days (minimum 48 hours). In the period 3 to 5 months post-PVI, patients will receive another Holter monitor for up to 4 consecutive days (minimum 48 hours). After completion of the second Holter monitoring period, the study will end for the patient. The follow-up period after ICM insertion will be at least 6 months.

Main study parameters/endpoints: 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 endpoint is the freedom from ICM- or insertion-related complications at 6 months post-ICM insertion.

### Doel van het onderzoek

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.

**Onderzoeksopzet**

Start 01-12-2019, FPI 18-12-2019
Inclusion period 9 months scheduled
Follow-up minimal 6 months after ICM implantation in last patient included

**Onderzoeksproduct en/of interventie**

Implantation of the BioMonitor III ICM device.

# Contactpersonen

## Publiek

Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Diagnosis of paroxysmal or persistent AF
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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Diagnosis of long-standing persistent AF
2. Subjects implanted with a previous ICM, pacemaker, implantable cardioverter defibrillator 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

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-12-2019 |
| Aantal proefpersonen: | 30 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nee

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 03-06-2019 |

Soort: Eerste indiening

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48234
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7777 |
| CCMO | NL70462.078.19 |
| OMON | NL-OMON48234 |

# Resultaten