

# Reveal AF

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See protocol page 9 This study designed to determine, via continuous monitoring with the Reveal XT implantable cardiac monitor (ICM) or newer approved version, the incidence of atrial fibrillation (AF) in patients suspected to be at high risk for...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cardiac arrhythmias
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38709

### Source

ToetsingOnline

### Brief title

Reveal AF

### Condition

- Cardiac arrhythmias

### Synonym

Atrial Fibrillation

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medtronic Trading NL BV

**Source(s) of monetary or material Support:** Medtronic

### Intervention

**Keyword:** Atrial Fibrillation (AF), Cardiac Arrhythmias, Implantable Cardiac Monitor (ICM)

## Outcome measures

### Primary outcome

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Primary objective

Determine the incidence rate of atrial fibrillation lasting greater than or equal to six minutes in patients who are at high risk of having atrial fibrillation.

### Secondary outcome

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Secondary objectives

- \* Identify predictors of AF onset in patients who are at high risk of having atrial fibrillation.
- \* Characterize the timing and nature of clinical actions relative to detection of AF in patients who are at high risk of having atrial fibrillation.

## Study description

### Background summary

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Atrial fibrillation (AF) is the most common diagnosed cardiac arrhythmia. AF is associated with significant morbidity and mortality due to cerebrovascular complications such as stroke; which lead to a substantial economic impact on the health care system. Therefore, the ability to identify AF is paramount for guiding preventative therapy decisions in patients suspected of, or who have clinical risk factors for having AF or a stroke.

However, the incidence of AF in patients suspected to be at high risk for having AF is not known. Several aspects make AF difficult to diagnosis, such as patient symptoms not being reliably correlated with AF episodes, the frequency of the episodes and frequency of ECG monitoring. Continuous cardiac monitoring may provide an important tool in both the diagnosis and follow-up management of AF.

## **Study objective**

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This study designed to determine, via continuous monitoring with the Reveal XT implantable cardiac monitor (ICM) or newer approved version, the incidence of atrial fibrillation (AF) in patients suspected to be at high risk for having AF and to understand how physicians manage these patients once AF has been detected. Furthermore, the study will seek to identify what patient characteristics are most predictive of developing AF. This information may facilitate the ability to identify those patients that are at highest risk for developing AF, and for whom Reveal ICM may be most beneficial and potentially cost saving.

## **Study design**

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The REVEAL AF study is a prospective, single arm, open-label, multicenter, post-market interventional clinical study. The study is expected to be conducted at approximately 60 clinical centers located in the United States (~45 centers) and Europe (~15 centers). Up to 450 subjects are planned to be enrolled into the study, to have approximately 400 patients implanted with the Reveal ICM.

Subjects will have required follow up visits at baseline, implant, 6 months, 12 months, 18 months (24 and 30 months). Follow-up will continue until the last subject has completed the 18 month follow-up.

## **Intervention**

Interventions are;

- Questionnaire (EQ5D) at baseline and the (unplanned) follow-ups
- blood collection at baseline
- 24h ECG monitoring at baseline if the subject has not had one within the previous 90 days prior to enrollment
- echo at baseline if the subject has not had one within the previous 6 months prior to enrollment

## **Study burden and risks**

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All the equipment and the implantable devices in the REVEAL AF study are market-released and are used in accordance with medical, technical, and ethical standards and in accordance with their approved and intended use. There are no incremental risks introduced to the subject as a result of participation in the REVEAL AF study. There are potential risks and discomforts associated with receiving a subcutaneous insertable cardiac monitor.

## Contacts

### Public

Medtronic Trading NL BV

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NL

### Scientific

Medtronic Trading NL BV

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NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

\* Patient meets the approved indications to receive the Reveal ICM

- \* Patient is suspected, based on symptomatology and/or demographics, of having atrial fibrillation or at high risk of having AF, as determined by the clinical investigator
- \* Patient has a CHADS2 score  $\geq 3$  OR has a CHADS2 score = 2 with at least one of the following documented:
  - o Coronary artery disease
  - o Renal impairment (GFR 30-60 ml/min)
  - o Sleep apnea
  - o COPD

## Exclusion criteria

- \* Patient has a documented history of AF or atrial flutter
- \* Patient had an ischemic stroke or TIA within past year prior to enrollment
- \* Patient has a history of a hemorrhagic stroke
- \* Patient is currently implanted with an IPG, ICD, CRT-P, or CRT-D device
- \* NYHA Class IV Heart Failure patient
- \* Patient had heart surgery within previous 90 days prior to enrollment
- \* Patient had an MI within the previous 90 days prior to enrollment
- \* Patient is taking chronic immuno-suppressant therapy
- \* Patient is taking an anti-arrhythmic drug
- \* Patient is contraindicated for long term anticoagulation medication
- \* Patient is taking a long-term anticoagulation medication

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-11-2013

Enrollment: 30

Type: Actual

## Medical products/devices used

Generic name: Reveal XT;Implantable Cardiac Monitor (ICM)  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
Date: 14-11-2013  
Application type: First submission  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO  
Date: 27-02-2014  
Application type: Amendment  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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
ClinicalTrials.gov	NCT01727297
CCMO	NL44898.060.13