Reveal AF

Published: 14-11-2013
Last updated: 22-04-2024

See protocol page 9This 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...

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

See protocol page 14

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

See protocol page 14

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

See protocol page 9-10

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

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 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

See protocol page 9

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 wil continue until the last subject has completed the 18 month follow-up.

Intervention

Interverstions are;
- Questionnaire (EQ5D) at basline 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

See protocol page 34-35

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

Earl Bakkenstraat 10
Heerlen 6422 PJ
NL
Scientific
Medtronic Trading NL BV

Earl Bakkenstraat 10
Heerlen 6422 PJ
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 >= 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