Determining Accuracy and Trending Characterization of AF

Published: 25-09-2012
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The purpose of this clinical investigation is to assess the accuracy of the Confirm DM2102 ICM in the detection of episodes of Atrial Fibrillation (AF).

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

Summary

ID

NL-OMON37262

Source
ToetsingOnline

Brief title
DETECT AF

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation, Palpitations

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: Atrium fibrillation, Implantable cardiac monitor, sensitivity

Outcome measures

Primary outcome

To assess SJM Confirm ICM performance through the sensitivity and positive

predictive values of AF episodes of at least 2 minutes in length,

utilizing the data collected during the Holter recording.

Secondary outcome

- To assess SJM Confirm ICM performance through the specificity and negative

predictive values, utilizing the data collected during the Holter

recording.

- To assess AF detection of episodes at least 6 minutes in length

Study description

Background summary

Atrial Fibrillation (AF) is the most commonly diagnosed arrhythmia. ECG monitoring is recommended for diagnosis of AF.Tools for monitoring include Holter monitoring patient- and automatically activated devices, external loop recorders and implantable cardiac monitors. External monitoring is subject to patient compliance which can be limiting depending on the duration of the monitoring and the follow-up scheme used.
Implantable Cardiac Monitors (ICM) have been used as a way to continuously monitor cardiac rhythm especially in case of unexplained syncope. Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias or patients who experience transient symptoms that may suggest a cardiac arrhythmia can benefit from the minimally invasive implantable subcutaneous monitoring device.
SJM Confirm ICM, DM2102, is a new ICM that includes an AF detection feature and diagnostics.
This study aims to assess the performance of this device in a clinical setting.

Study objective

The purpose of this clinical investigation is to assess the accuracy of the

Confirm DM2102 ICM in the detection of episodes of Atrial Fibrillation (AF).

Study design

This is an international, multi-center, prospective, non-randomized, observational investigation.

Study burden and risks

The subject is not exposed to additional risk, but might be hindered by carrying the holter recorder during the 4 day holter period.

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

- The subject has been implanted with a SJM Confirm ICM, DM2102.
- The subject has or is suspected to have paroxysmal AF.
- The subject is * 18 years of age.
- The subject is willing and able to provide written Informed Consent (prior to any investigational related procedure).

Exclusion criteria

- The subject has persistent (>7 days and <1 year or AF requiring cardioversion), longstanding persistent (continuous AF >1 year) or permanent AF (not attempting to restore sinus rhythm).
- The subject has AF of reversible etiology (e.g. electrolyte imbalance, thyroid disease).
- The subject has a contraindication to Holter recording.
- The subject has already received an active implantable medical device other than the SJM Confirm ICM, DM2102.
- The subject is unable to comply with the follow up schedule.
- The subject is participating in another investigational device or drug investigation.
- The subject is pregnant or is planning to become pregnant during the duration of the investigation.

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):	08-02-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-01-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL41093.098.12