Confirm RxTM Insertable Cardiac Monitor SMART Registry

Published: 08-11-2018
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The purpose of the Confirm RxTM SMART Registry is to collect real world data to assess the safety and performance of the Confirm RxTM Insertable Cardiac Monitor (ICM) and system over a 12 month period.

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

Summary

ID

NL-OMON48966

Source
ToetsingOnline

Brief title
SMART Registry

Condition

- Cardiac arrhythmias

Synonym
dizzyness, Syncope

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Confirm Rx, Heart rythm disorders, Syncope

Outcome measures

Primary outcome

The primary safety endpoint is the freedom from serious adverse device effects (SADEs) and procedure related serious adverse events (SAEs) through 1 month post insertion procedure is greater than the pre-specified performance goal.

Secondary outcome

• Freedom from device SADEs and procedure related SAEs through 12 months post insertion procedure.

• R wave amplitude at scheduled follow-up intervals through 12 months post insertion procedure.

Study description

Background summary

Insertable cardiac monitors (ICM) have been on the market for a while to diagnose Complaints like syncope, dizzyness, fatique, arithmias like AF and in case of cryptogenic stroke. The latest generation ICM has a volume which has been reduced by 78% and is injectable. This should theoretically reduce the infection rate.
This study will be conducted to evaluate the safety profile up to 12 months post insertion and the clinical utility of this ICM device.

Furthermore the first 85 subjects in the study are a PMCF requirement.

Study objective

The purpose of the Confirm RxTM SMART Registry is to collect real world data to assess the safety and performance of the Confirm RxTM Insertable Cardiac Monitor (ICM) and system over a 12 month period.

Study design

This is a prospective, single arm, multi-center registry study of subjects with a Confirm Rx* ICM device inserted

Study burden and risks

There is no additional risk in participating in the study. The burden consists of filling out different questionnaires at baseline and the 1 and 12 month follow up visits.
For subjects who participate in the Holter substudy the burden consists of wearing the Holter device for 4 days.

Contacts

Public
St. Jude Medical

Standaardruiter 13
VEENENDAAL 3905 PT
NL
Scientific
St. Jude Medical

Standaardruiter 13
VEENENDAAL 3905 PT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Have an approved indication for continuous arrhythmia monitoring with an ICM.
• Have a cellular phone or the ability or willing to use a St. Jude Medical mobile transmitter that is compatible with the MyMerlin* App and able to communicate with the Confirm RxTM ICM device. If a subject doesn*t have a cell phone or loses their cell phone, then the site can provide a St. Jude Medical mobile transmitter to the subject. The study will not provide cell phones.
• Have the ability to provide informed consent for study participation and be willing and able to comply with the prescribed follow-up tests and schedule of evaluations.
• Are 18 years of age or older, or of legal age to give informed consent specific to state and national law.

Exclusion criteria

• Subject is implanted with or indicated for implant with a pacemaker, implantable cardioverter defibrillator (ICD), or cardiac resynchronization therapy (CRT) device.
• Enrolled or intend to participate in a clinical drug and/or device study, which could confound the results of this trial as determined by the sponsor, during the course of this clinical study.
• Have a life expectancy of less than 1 year due to any condition.
• Have a previous ICM placement.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2019

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-02-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	22-05-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-09-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NCT03505801
CCMO	NL65984.075.18