Clinical evaluation of Remote monitoring with dirEct Alerts* to reduCe Time from event to clinical decision

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

Summary

ID

NL-OMON36356

Source
ToetsingOnline

Brief title
REACT

Condition

- Cardiac arrhythmias

Synonym
Detection of a heart event via Merlin.net PCN / detection of a heart event via home monitoring

Research involving
Human

Sponsors and support

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

Intervention

Keyword: - clinical decision, - Direct Alerts, - ICD / CRT-D, - Merlin.net Patient Care System

Outcome measures

Primary outcome

The primary endpoint for the investigation is the time between the detection of an event and the point in time when the physician or delegate takes a clinical decision.

Detection of an event =

The time when the implanted device (ICD or CRT-D) triggers an alert. The alert is based on a change in value outside the default or programmed limits.

Clinical decision =

When the physician or delegate determines if an action is required to follow-up on the event; or an action is not required to follow-up on the event

Secondary outcome

* % of all events for which a clinical decision could be taken based on the device data retrieved during the Remote Monitoring review.

* Physician or delegate time spent during in-clinic and remote follow up (both protocol required scheduled and unscheduled follow ups) and daily remote monitoring review.

Study description

Background summary

Previous studies have shown the effectiveness of the implantable cardioverter defibrillator (ICD) in both primary and secondary prevention of sudden cardiac death and have influenced the number of patients implanted with devices significantly. This expanding population of patients with implantable cardiac devices requires special care and regular follow up. The current guidelines for the management of implanted device require interrogation and monitoring of the device 2-4 times per year. With the latest generation of devices, clinicians are able to follow up (FU) their patients with ICDs remotely, with fewer in-clinic consultations. Several studies have shown that this may result in more efficient FU with cost-savings for the health care payer

Besides allowing remote follow up, the newest devices also have the capability of automatic alerting of silent but potentially dangerous events.
In the literature it is clear that an automatic alerting capability could provide early detection and notification of the clinician of these silent events. However, there are few data available on the positive effect of automatic alerts on the time to clinical decision making.
This investigation is developed to investigate if the detection of silent cardiac events will occur earlier with the daily alerts notification feature of St Jude Medical (Remote monitoring) and if so, if it will lead to more timely management. Early detection and resolution of these events could then improve patient care.

Study objective

St. Jude Medical developed the Merlin.net* Patient Care Network (Merlin.net* PCN) to augment or replace routine scheduled in-clinic visits.

This investigation is designed with the hypothesis that detection of events (system integrity and diagnostic related) through Direct Alerts* via Remote Monitoring allow clinicians an earlier opportunity to address and resolve events and may therefore improve patient care.

This investigation is a randomized, prospective, open, parallel, multicenter design.

Study design

Randomization
* Randomization is stratified by center and by implanted device (ICD or CRT-D).
* Patients are randomized in a 1:1 fashion to either the control or remote monitoring group.
* Control Group:
The monitoring of alerts (system integrity and diagnostics) will be programmed

ON in the patient*s implanted device. The Remote Monitoring Direct Alerts will be programmed OFF in the Merlin.Net PCN.
* Remote Monitoring Group:
The monitoring of alerts (system integrity and diagnostic) will be programmed ON in the patient*s implanted device. The Remote Monitoring Direct Alerts will be turned ON in the Merlin.Net PCN.

Intervention

ICD / CRT-D implantation before actual start of the trial.

Study burden and risks

Participation in the trial does not expose patient to additional risks

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

- Patient meets ACC/AHA/ESC guidelines for implantable cardioverter defibrillator (ICD) of cardiac resynchronization therapy (CRT-D) device
- Patient is recently (*2 weeks) implanted with a SJM device compatible with the Merlin.net* PCN (inclusive of upgrade from ICD to CRT-D or an implantable pulse generator change)
- Patient has a life expectancy of greater than 12 months (based on the physician's discretion)
- Patient is mentally capable to participate in the investigation (based on the physician's dicretion)
- Patient is 18 years of age or older

Exclusion criteria

- Patient is being actively considered for cardiac transplantation
- Patient has primary valvular disease that has not been corrected
- Patient had a myocardial infarction within the last month
- Patient had unstable angina within the last month
- Patient has had Coronary Artery Bypass Grafting (CABG) within the last month
- Patient had a Percutaneous Coronary Angioplasty (PTCA) within the last month
- Patient is pregnant

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-11-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Merlin.net Patient Care Network (PCN) compatible with ICD / CRT-D device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-05-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-10-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-03-2011
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	NL31122.098.10