MISSION! REMOTE Telemonitoring of Implantable Cardioverter Defibrillators: A randomized controlled trial

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Reduction of ICD/CRT-D follow-up by telemonitoring in a feasible way.

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

Summary

ID

NL-OMON32998

Source
ToetsingOnline

Brief title
MISSION! REMOTE

Condition

- Cardiac arrhythmias

Synonym
Cardiac Arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Home Monitoring, Implantable Cardioverter Defibrillator, Remote Monitoring, Telemonitoring

Outcome measures

Primary outcome

The primary purpose of this study is to evaluate whether telemonitoring can decrease the follow-up burden for ICD/CRT-D patients and clinic. Therefore, the number of interrogations will be assessed. Secondly the feasibility of telemonitoring will be tested by assessing the number of data-transmissions, patient compliance, ease of use and satisfaction.

Secondary outcome

The first secondary objective will be to assess the value of asymptomatic events and alerts, as detected by telemonitoring. Early detection and resolution of silent events hold obvious promise in the advancement of patient care.

In the second secondary objective, the potential cost benefit of telemonitoring will be assessed.

Thirdly, the additional information acquired by telemonitoring will be assessed. The ICDs/CRT-Ds used in this study are equipped with several monitoring features, which are innovative but not (yet) implemented in current guidelines

Study description

Background summary

The increase of indicications for ICDs/CRT-Ds has led to an expansion of ICD/CRT-D implantations worldwide resulting in an immense follow-up burden for the outpatient clinic. Next to this, for patients having an ICD/CRT-D means frequent device follow-up, up to 5 times during the first year. To reduce the follow-up burden for patient and clinic, telemonitoring systems were developed. Until now, only one randomized controlled trial has yet been performed demonstrating that telemonitoring is as safe as standard monitoring of ICD/CRT-D patientes. In this randomized controlled trial the feasibility and follow-up reduction of telemonitoring will be assessed.

Study objective

Reduction of ICD/CRT-D follow-up by telemonitoring in a feasible way.

Study design

This is a prospective, randomized controlled, two-arm study enrolling patients with ICD/CRT-D implants.
A total of 300 patients will be enrolled in this study at the Leiden University Medical Center (LUMC) and at implantation patients are randomized for telemonitoring or conventional, calendar-based follow-up. After the first randomization, the patients enrolled in the telemonitoring group will have another randomization for telemonitoring system. In the telemonitoring group one group will use the system of Biotronik and the other the system of Medtronic and consequently a Biotronik ICD/CRT-D or a Medtronic ICD/CRT-D will be implanted. In the control group, a Boston Scientific ICD/CRT-D will be implanted

Study burden and risks

Since two out of five conventional, calendar-based ICD-interrogations at our clinic will be replaced by telemonitoring interrogations, a potential risk is the lesser direct contact with the patient. However, on the other side, unnoticed technical ICD/CRT-D problems or arrhythmias will be earlier detected by telemonitoring.

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

Indication for ICD or CRT-D
18 years of older
Capability to use either telemonitoring system throughout 12 months (Biotronik's Home Monitoring or Medtronic's CareLink)

Exclusion criteria

Congenital heart disease
Instable Medical condition

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-05-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL26718.058.09