Remote Monitoring of Heart Failure Patients with a Cardiovascular Implantable Electronic Device: The Patient Perspective (REMOTE-CIED study)

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The primary objective of this study is:to evaluate the effect of RPM + in-clinic follow-up versus in-clinic follow-up only on patient-reported health status/quality of life after implantation with an ICD/CRT-D device. The secondary objectives are: 1...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON44924

Source
ToetsingOnline

Brief title
REMOTE-CIED

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Boston Scientific,research grant

Intervention

Keyword: Heart failure, Patient perspective, Quality of life, Remote Monitoring

Outcome measures

Primary outcome

Primary:

disease-specific health status, device acceptance

Secondary outcome

Secondary:

1) satisfaction with RPM

2) cost-effectiveness.

Study description

Background summary

Cardiovascular implantable electronic device therapy, in particular implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT), has gained increasing acceptance and is now implanted on a large scale in a subgroup of patients with congestive heart failure (CHF). In order to reduce the workload for the outpatient clinics, remote patient monitoring (RPM) has become a widely used method to check on these patients. RPM systems can interrogate the ICD/CRT-D device automatically and send the data from the patients* home to the physician, thereby reducing in-clinic follow-ups. Studies have shown that the remote monitoring of device and CHF parameters (i.e., sudden changes in weight, blood pressure and other clinical parameters) reduces health care utilization, without impairing patient safety. However, whether these RPM effects translate to improved patient-reported outcomes is uncertain, and no study to date has examined the effect of clinical and psychological factors on patient acceptance and satisfaction with RPM.

Study objective

The primary objective of this study is:
to evaluate the effect of RPM + in-clinic follow-up versus in-clinic follow-up only on patient-reported health status/quality of life after implantation with an ICD/CRT-D device.

The secondary objectives are:
1) to identify subgroups of patients who are or are not satisfied with RPM due to specific clinical and psychological factors
2) to investigate the cost-effectiveness of RPM + in-clinic follow-up compared to in-clinic follow-up only

Study design

The study will be a multicenter, randomized controlled study. Patients will be randomized to either RPM + in-clinic follow-up (RPM group) or in-clinic follow-up only (In-Clinic group). Both groups will be asked to complete a set of standardized and validated questionnaires at 5 time points (i.e., T0=1-2 weeks, T1=3 months, T2=6 months, T3=12 months, and T4=24 months post-implantation). The RPM group will receive the LATITUDE® Patient Management system 4-8 weeks after implantation. The In-Clinic group will visit the outpatient clinic every 3-6 months, as part of standard clinical practice. The RPM group will visit the outpatient clinic only at 12 and 24 months post-implantation, the other check-ups will be performed remotely.

Intervention

For this protocol the sponsor will use a registred/certified device (implant) for all patients and compare 2 groups. Patients will be randomized to either

1. usual care with RPM *Remote patient monitoring* which is also registered/certified
2. usual care without RPM.

Study burden and risks

The risk associated with participation in the study is negligible as two different types of care as usual will be compared with each other. No specific (invasive) study procedures will be performed that causes any safety risks. The patient commitment is comprised of completing a set of questionnaires at five time points. These questionnaires are handed to them at discharge from the hospital after implantation (T0) or sent to them by mail (T1-T4). Patients will fill in all questionnaires at home, which will take approximately 45 minutes per time point.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-First time ICD or CRT-D implanted at one of the participating centers
-LVEF * 35% (assessed max. 12 months prior to implantation)
-NYHA functional class II or III symptoms at time of implantation
-ICD/CRT-D device compatible with the LATITUDE® Patient Management system from Boston Scientific (e.g., COGNIS®)

Exclusion criteria

-Younger than 18 or older than 85 years of age
-On the waiting list for heart transplantation
-History of psychiatric illness other than affective/anxiety disorders

-Inability to fill out the questionnaires due to cognitive impairments (e.g. dementia)
-Insufficient knowledge of the language to fill in the questionnaires

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2013
Enrollment:	347
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-09-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-04-2014
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-08-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NCT01691586
CCMO	NL38544.041.12