Monitoring Resynchronization in Cardiac Patients

Published: 31-03-2010
Last updated: 04-05-2024

Demonstrate that the remote management system (Carelink, study group) reduces the time from device detected event onset to clinicaldecision for arrhythmias, cardiovascular disease progression,and system issues compared to patients receiving only in-...

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

Summary

ID

NL-OMON35090

Source
ToetsingOnline

Brief title
More-Care

Condition

- Cardiac arrhythmias

Synonym
heart failure, heart rhythm disturbances

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Carelink, CRT-D, heart failure

Outcome measures

Primary outcome

Phase 1.

Primary Endpoint

Mean time between event onset time and clinical decision for each subject.

Phase 2

Secondary Endpoints

1. mean time from clinical decision for any relevant event to the end of the event, adjudicated by the Event Adjudication Committee.

2. QoL as measured by the MNLWHF and the EQ-5D questionnaires on a per subject basis.

Secondary outcome

Phase 2.

Primary Endpoint: death from any cause, cardiovascular and device-related hospitalizations (at least 48 hours stay), calculated using a time to first event analysis.

Phase 2:

Secondary Endpoints.

1. Rate of hospitalizations on a per subject basis.

2. Number of days spent in hospital (including hospitalizations,

exams, in-office visits and ED admissions) on a per subject

basis.

3. Costs of healthcare resources (including hospitalizations,

exams, in-office visits and ED admissions) on a per subject

basis.

4. QoL as measured by the MNLWHF and the EQ-5D

questionnaires a per subject basis.

5. Proportion of patients who receive optimal medical treatment

for AF.

Study description

Background summary

Remote CRT-D follow-up (via the Carelink network) is available on the market. The main aim of this study is to demonstrate that the remote management strategy is superior to the standard strategy, both in terms of clinical effectiveness and total healthcare system utilisation.

Study objective

Demonstrate that the remote management system (Carelink, study group) reduces the time from device detected event onset to clinical
decision for arrhythmias, cardiovascular disease progression,and system issues compared to patients receiving only in-office
care (control group).

Study design

MORE-CARE is an international, prospective, multi-center, randomized,

controlled trial.
Patients will be randomized 1:1 into 2 groups:
1) Control group
2) Study group
Up to 1721 patients will be included and followed up for 24 months (average)
Approximately 80 center in EMEA will participate in the study, and this may be extended to other sites outside EMEA..

Intervention

EXCLUSION CRITERIA
1) Inability to fully understand the instructions relating to remote monitoring using CareLink Network.
2) Permanent AT/AF.
3) Patient has been previously implanted with a CRT/CRT-D device.
4) Patient has medical conditions that would limit study participation.
5) Patient is less than 18 years of age.
6) Patient is enrolled in or intends to participate in another clinical trial that
may have an impact on the study endpoints.
7) Patient meets any exclusion criteria required by local law.
8) Inability or refusal to sign a patient informed consent form.
9) Patient's life expectancy is less than one year in the opinion of the physician
10) Patient is pregnant or breastfeeding.

Study burden and risks

There are no additional risks associated with participation in this study (the CRT-D device and Carelink network are market-released). The results of this study will show if heart failure treatment with Carelink is better and more efficient than heartfailure treatment without Carelink.

Contacts

Public
Medtronic Trading NL BV

Postbus 2542
6401 DA Heerlen
NL
Scientific
Medtronic Trading NL BV

Postbus 2542
6401 DA Heerlen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with a CRT-D indication
Patient is willing and able to use the Medtronic Carelink Network

Exclusion criteria

- Permanent AT/AF
- CRT-D replacement patients

Study design

Design

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

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2010
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	CRT-D
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-03-2010
Application type:	First submission
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
ClinicalTrials.gov	NCT00885677
CCMO	NL30703.098.09