European Health Economic Trial on home monitoring in ICD and CRT-D patients

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This amendment (extension to CRT-D subjects) aims to assess the economic effects of HM technology vs. classical follow-up of CRT-D patients from two perspectives: 1) the cost-effectiveness for the payer of health care, and 2) the economic impact on...

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

Summary

ID

NL-OMON38297

Source
ToetsingOnline

Brief title
EuroEco

Condition

- Cardiac arrhythmias

Synonym
ventricular fibrillation, ventricular tachycardia

Research involving
Human

Sponsors and support

Primary sponsor: Biotronik
Source(s) of monetary or material Support: BIOTRONIK

Intervention

Keyword: CRT-D (implantable cardioverter defibrillator with cardiac resynchronization therapy), economic effect, ICD (implantable cardioverter defibrillator), telemonitoring

Outcome measures

Primary outcome

Difference in direct costs of CRT-D follow-up (valued in Euro) for physicians / hospitals, with Home Monitoring based patient management vs. classical follow-up.

The endpoints of the study will not be changed in the CRT extension amendement.

Secondary outcome

Effective financial impact on hospitals / physicians, by also factoring in the actual follow-up related reimbursement for each center / region.

Average number of in-hospital followup visits per patient

Time to first in-hospital FU visit beyond the first post-implantation visit

Proportion of in-hospital consultations with relevant findings (i.e. necessitating changes in medical therapy, device programming or rehospitalisations / interventions).

Proportion of patients with HM triggered interventions that would have been

discovered only at scheduled follow-up without remote monitoring.

Incidence of inappropriate ICD shocks.

Changes in Quality Of Life (SF-36 QOL) from baseline to 12 and to 24 months

after enrolment.

Study description

Background summary

Remote monitoring of CRT-D function and patient status via *Home Monitoring* (HM) offers the potential benefit of more effective follow-up and increased safety through prevention of potential deleterious events. Moreover, it could allow for more efficient follow-up, with potential costsavings or the health care payer. It requires however a new follow-up model with fewer patients seen during routine in hospital consultations but with systematic and regular remote follow-up.
Such a new model may have an important impact on both costs and income of physicians and hospitals (via reimbursement).
For physicians and hospitals, the cost of follow-up is comprised of personnel cost (dependent on the time spent by physicians and paramedics), overhead costs for space and personnel used, and technology-related costs. Income will be defined by the existing reimbursement regulations. With current reimbursement policies in most countries, however, the economic impact of HM for physicians / hospitals may be negative (due to reduced income for routine follow-up visits).

For the payer of health care services, the total sum of follow-up related reimbursement will constitute the cost side of the equation (including rehospitalisation costs). Effectiveness for the health care provider will depend on the quality of the follow-up, as can be measured by e.g. mortality, average number of in-hospital visits per patient and proportion of these with relevant findings, HM-triggered interventions, patient QOL, or incidence of inappropriate ICD shocks. HM may lead to an improved cost-effectiveness for the health care provider, largely through a reduction of costs.

The current approved version of the protocol (version 1.1 dd14NOV2007) has enrolled his 312 subjects with a single- or double-chamber ICD. Currently more and more triple-chamber ICDs are routinely implanted (CRT-D: ICD with Cardiac Resynchronization Therapy) however no scientific data is available on the cost effectiveness of the use of telemonitoring in this CRT patient population. Therefore the current version of the protocol (version 1.1 dd14NOV2007) wil be amanded to include 104 subjects with an CRT-D indication (protocol version 1.2 dd16FEB2012).

This amendmentl may provide data warranting a change in the guidelines for use of CRT-D devices featuring HM, in that HM functionality may justify a prolongation of the time interval between statutory routine in-clinic FU visits. This, coupled with the fact that the information provided by HM helps physicians recognize some otherwise unsuspected needs for additional FU visits, may ultimately result in better and more cost-effective health care for all involved (patients, providers and payers).

Study objective

This amendment (extension to CRT-D subjects) aims to assess the economic effects of HM technology vs. classical follow-up of CRT-D patients from two perspectives: 1) the cost-effectiveness for the payer of health care, and 2) the economic impact on the physician, hospital and patient.

Patient follow-up will be managed according to a pre-defined algorithm based on previous BIOTRONIK trial data aiming
at reducing in-hospital visits as much as possible while retaining maximal effectiveness and safety.

Study design

Prospective.
Multicenter.
International.
Randomized (1:1).
Open-label.

All patients will receive a commercially available BIOTRONIK Lumax HF-T CRT-D device.
Patients will be randomized to HM=ON or HM=OFF.

Intervention

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Study burden and risks

All patients are indicated for a CRT-D (BIOTRONIK Lumax HF-T).
All devices used are CE-marked. No additional risks are related to ICD implantation due to study participation. No deviation from the currently common therapy standard is to be expected due to study participation (with or without Home Monitoring/ HM= On or HM=OFF).

The Quality Of Life (SF-36 QOL) will be evaluated 3 times during the 2 year study period (baseline, 12 and 24 month follow up).

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

Patients with indication for de novo CRT-D implantation,
Patient information and informed consent.

Exclusion criteria

Patients who had a cardiac device implanted before (upgrade, device replacement).
LIfe expectancy < 12 month.
Planned heart transplantation.
NYHA class IV.
Minors and pregnant women.
Patients who are already enrolled in another study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	LUMAX HF-T implantable Triple- chamber cardioverter defibrillator

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-05-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	12-12-2012
Application type:	Amendment
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
ClinicalTrials.gov	NCT00776087
CCMO	NL25720.058.08