Echocardiography Guided Cardiac Resynchronization Therapy Clinical Investigation

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The EchoCRT trial evaluates the effects of Cardiac Resynchronization Therapy (CRT) on mortality and morbidity of subjects with heart failure due to left ventricular systolic dysfunction, already receiving optimized HF medication, with a narrow QRS...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON32443

Source
ToetsingOnline

Brief title
EchoCRT

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Heart Failure, weakened heart muscle

Research involving
Human

Sponsors and support

Primary sponsor: BIOTRONIK Inc. - clinical study department
Source(s) of monetary or material Support: Biotronik

Intervention

Keyword: Cardiac Resynchronization Therapy, Heart Failure, normal QRS, Ventricular Dyssynchrony

Outcome measures

Primary outcome

Primary Outcome Measures:

The primary efficacy endpoint will evaluate the effect of CRT=ON versus CRT=OFF in time to event of a combined endpoint of all-cause mortality or first hospitalization for worsening heart failure. [Time Frame: Full study duration (event driven trial). Minimum 1 year follow-up and expected median patient follow-up duration of 2 years.]

The primary safety endpoint will evaluate the complication-free rate at 6 months of the Lumax HF-T CRT-D devices in the narrow QRS subject population. [Time Frame: 6 months]

Secondary outcome

Secondary Outcome Measures:

Evaluate the all-cause mortality rate between the CRT=ON compared to CRT=OFF group.

Evaluate the effects of CRT=ON compared to CRT=OFF on the rate of hospitalization for worsening heart failure.

Evaluate the effects of CRT=ON compared to CRT=OFF in relation to the change in NYHA classification.

Evaluate the effects of CRT=ON compared to CRT=OFF in relation to the change in

the Minnesota Living with Heart Failure (MLHF) Quality of Life Questionnaire.

Evaluate the effects of CRT=ON compared to CRT=OFF in relation to a composite

endpoint of all-cause mortality, hospitalization for worsening heart failure

and change in the MLHF Quality of Life Questionnaire.

Study description

Background summary

Previous randomized clinical trials with CRT provided evidence of an improvement of HF symptoms, exercise capacity, quality of life and a relative and absolute reduction in all-cause mortality. CRT has been included in the official guidelines for the management of heart failure subjects. These guidelines currently still recommend a QRS width of > 120ms as a criterion for prescription of CRT. Results of more recent studies, however, indicate that the QRS width alone is a weak marker for LV dyssynchrony and a poor guide to treatment benefit for CRT. So far, only single center trials and a small multi-center randomised controlled pilot study have been conducted evaluating CRT in subjects with HF and narrow QRS. Thus, CRT treatment could be of therapeutic benefit in the majority of HF patients with a narrow QRS width (<120 ms), of whom up to 50% exhibit LV dyssynchrony.

Study objective

The EchoCRT trial evaluates the effects of Cardiac Resynchronization Therapy (CRT) on mortality and morbidity of subjects with heart failure due to left ventricular systolic dysfunction, already receiving optimized HF medication, with a narrow QRS width (< 130 ms) and echocardiographic evidence of ventricular dyssynchrony

Study design

Study Design: Treatment, Randomized, Double Blind (Subject, Investigator, Outcomes Assessor), Active Control, Parallel Assignment, Safety/Efficacy Study
All patients will receive a commercially available BIOTRONIK Lumax HF-T CRT-D system with ICD back-up enabled. Patients will be randomized to CRT=ON or CRT=OFF.

Intervention

Study Type: interventional

Device: Implantable Cardioverter Defibrillator with Cardiac Resynchronization Therapy (BIOTRONIK Lumax HF-T CRT-D)

Study burden and risks

All patients are indicated for an ICD and wil be implanted with a biventricular ICD system (CRT-D: BIOTRONIK Lumax HF-T). All devices used are CE marked. Potential risks for the patient related to this study include those typical of a CRT-D system implant (more specifically the positioning of the left ventricular electrode). CRT therapy will be randomised to CRT=ON and CRT=OFF group. 50% of patients will not benefit from the left ventricular lead implant whereas the other 50% have the potential to benefit from the CRT therapy. Approximately 1 month after the randomisation the investigator will evaluate the CRT-D system, the HF medication and perform a clinical evaluation on the HF status. During a period of 24 months these investigations are repeated every 3 months. The HF treatment as described in the protocol is in accordance with the current medical treatment of HF patients. Additionally there is: an echocardiogram (at baseline, 6 and 12 month), 6 minute walk test (baseline and at month 6, 12 and 24), BNP measurement (at baseline, 6 and 12 month) and a MLHF questionnaire (baseline and at month 3, 6, 12, 18 and 24). After the 24 month visit the patient is requested to return every 3 months for standard follow-up visits until the study is over.

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
systolic heart failure: LVEF < 35% and LVEDD > 55 mm
NYHA III-IV under optimal medical therapy
QRS < 130 ms
ventricular dyssynchrony measured by Echo + confirmed by Echo Core Lab
18 years of age or older

Exclusion criteria

Contraindication(s) to an ICD.
Already implanted with a pacemaker or an ICD
Bradycardia pacing indication
Pregnant, lactating or planning to become pregnant females.
CABG, PTCA, or MI within the past 3 months prior to enrollment or CABG or PTCA intervention planned in the next 3 months.
Irreversible brain damage from preexisting cerebral disease.
Reversible non-ischemic cardiomyopathy such as acute viral myocarditis.
Permanent 2º or 3º heart block.
Chagas disease.
Persistent, permanent, or paroxysmal atrial fibrillation within 1 month prior to enrollment.
Expected to receive heart transplantation within 6 months.
Have a life expectancy of less than 6 months
Creatinine > 2.5 mg/dL or liver failure

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Lumax HF-T implantable 3-chamber cardioverter/defibrillator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-02-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	03-09-2009
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	26-07-2012
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	NCT00683696
CCMO	NL25448.058.08