Clinical Investigation on differences in the magnitude of CRT response in WOmen versus MEN

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

Summary

ID

NL-OMON55752

Source
ToetsingOnline

Brief title
BIOWOMEN

Condition

- Heart failures

Synonym
Heart Failure: decreased pump function of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Biotronik
Source(s) of monetary or material Support: BIOTRONIK SE & Co.KG

Intervention

Keyword: Cardiac Resynchronization Therapy, Heart Failure

Outcome measures

Primary outcome

Information on the heart function and volumes as measured with standard

echocardiography: ejection fraction (%EF), volumes etc...

Secondary outcome

classification of HF status: NYHA I, II, III or IV

QOL test: Minesotta Living with Heart Failure Questionaire

exercise capacity test: 6 minute hall walk test

SAE reporting with focus on HF hospitalization, mortality..

composite HF score (modified Packer score)

basline ECG (QRS duration and morphology) as predictor for CRT response (males

vs females)

Study description

Background summary

Revision of the major published CRT and HF trials indicate that women are under-represented in HF trials compared to man, with the average women enrollment rate in between 25% and 30% of the total HF population. Sub-analyses of these big CRT trials (with only 25-30% of females) indicates that females could have a better response to CRT. Single center retrospective research has recently shown in a highly selective patient population (only non-ischemic patients with an LBBB) that females have a better response to CRT compared to men. We would like to study this prospectively in an unbiased "real life" HF patient population with an equal distribution of males/females. This could lead to gender specific selection criteria for CRT.

Study objective

The general objective is to study gender differences in the magnitude of CRT response in a HF population with an equal distribution of women and man in order to examine the interrelationship among CRT effect, gender and baseline clinical factors (e.g. like QRSd).
The primary objective is to study the magnitude of CRT response in women measured as a function of improvement in LVEF in order to demonstrate overall superiority of CRT response in women.

In the secondary objectives we will investigate gender differences based on:
- changes in major clinical variables during a 12M FU period in men and women.
- changes in Left Ventricular End Diastolic Volume (LVEDV) and Left Ventricular End Systolic Volume (LVESV)
- differences at baseline with regards of presence of inter/intra ventricular dyssynchrony, HF etiology (ischemic versus non-ischemic cardiomyopathy), QRS morphology (LBBB vs. RBBB) and QRSd in a group of CRT responders (female vs male)
- observational assessment of how key clinical variables are related to the patient's CRT response, to create a possible *gender specific* response model.
- the relationship between QRS duration and CRT response in men and women.

Study design

Observationel study to asses the HF status and CRT response over a period of 12 months with non-invasive daignostics (echocradiography, ECG, NYHA, QOL test, 6 minute hall walk test, SAE reporting...). Prospective research on an equal patient population of males/females from a real life patient poplation indicated for CRT.

Study burden and risks

The burden and risks associated with participation are limited as this is an observationel study with additional non-invasive diagnostics to asses the HF status over a period of 12 months in order to measure the CRT response:
- a standard echocardiography of the heart to asses the heart function and volumes: baseline, 6 and 12 month
- an ECG at baseline: QRS duration and morphology
- a 6 min hall walk test: baseline, 6 and 12 month
- a QOL questionair: baseline, 6 and 12 month
- patient self assesment (patient needs to indicate how he feels compared to before the CRT device implant)
these tests are performed during the normal in office FUPs scheduled to check the CRT device: a first check-up 2 months after CRT implantation and every 6 months. After 12 months the study is finished.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

indication for a "de novo" implantation of a CRT device according to ESC Guidelines
written informed consent

Exclusion criteria

CRT replacements or upgrades
Permanent Atrial Fibrilation
age < 18
NYHA IV
life expectancy less than 12 months

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2016
Enrollment:	94
Type:	Actual

Medical products/devices used

Generic name:	Cardiac Resynchronization Therapy (with Pacemaker or ICD)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-01-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-11-2018
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-04-2022
Application type:	Amendment
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	NCT02344420
CCMO	NL53026.058.15