Identifying markers for response to cardiac resynchronization therapy in the Maastricht University Medical Centre; a prospective follow-up study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON36624

Source
ToetsingOnline

Brief title
IMAR-CRT study

Condition

- Heart failures

Synonym
heart failure and left bundle branch block

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac Resynchronization Therapy, Heart Failure, Left Bundle Branch Block

Outcome measures

Primary outcome

- Prediction by the new composite algorithm of the degree of response on CRT, defined as %decrease in LVESV at 6 months

Secondary outcome

- Additional improvement in prediction of the degree of response by exploring secondary potential markers for response to CRT
- Prediction by the new composite algorithm of the degree of response on CRT, defined as %increase in LV ejection fraction (LVEF) points at 6 months
- Change in ECG and three-dimensional vectorcardiography (VCG) at 6 months of CRT
- Changes in NT-pro-BNP and other known and future biomarkers levels at 6 months of CRT
- Change in NYHA functional class at 6 months of CRT
- Change in Quality of Life scores assessed by means of the *Minnesota Living with Heart Failure Questionnaire* and EuroQol at 6 months of CRT
- Change in the six minutes hall walk test (6MWT) at 6 months of CRT
- Repolarization changes obtained with 3-dimensional VCG at 1, 5, 10 days, 1, 3 and 6 months of CRT
- Changes in echocardiographic parameters of diastolic heart function as well as heterogeneity in time to peak longitudinal strains at 1, 5, 10 days, 1, 3

and 6 months of CRT

- Occurrence of arrhythmias at 1, 5, 10 days, 1, 3 and 6 months of CRT

Study description

Background summary

In patients with heart failure and wide QRS-complex cardiac resynchronization therapy (CRT) is indicated. This therapy often results in restoration of a more synchronous ventricular contraction pattern, improves left ventricular (LV) systolic function and reverses ventricular remodeling in large groups of patients. At the individual level, the effect is difficult to predict and approximately one third of patients do not improve by this therapy. Moreover, diastolic function is hardly affected at all by CRT.

Study objective

The main aim of the present study is to validate a predictive multiparametric algorithm to predict the response to CRT in terms of the amount of decrease in LV end systolic volume (LVESV). The model combines typical left bundle branch block (LBBB) pattern on the electrocardiogram (ECG), interventricular mechanical delay, septal rebound stretch, QRS duration, non ischemic cardiomyopathy and estimated glomerular filtration rate (eGFR) (acronym: LISQNE). Our secondary objective is to retrospectively fine-tune the algorithm by evaluating other baseline indices and early predictors of CRT response.

Study design

This study comprises a prospective validation study with secondary post-hoc analyses.

Study burden and risks

Patients participating in this study need to visit the hospital one extra time on top of regular care. Furthermore, at two different time points blood samples will be collected by venapunction. In addition, physical examination (blood pressure, length and weight), echocardiography, electrocardiogram, 3-dimensional VCG, holter monitoring, reading out of pacemaker/ ICD, six minutes hall walk test and the Minnesota Living with Heart Failure Questionnaire and EuroQol will be obtained before implantation as well as 6 months after implantation. Besides small physical and psychological discomfort associated with the clinical investigations, no risks are caused by this

proposed study (only standard routine investigations).

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

Inclusion criteria are:
* Indication for CRT (made by the cardiologist independently of the study)
* Age >18 years
* Capable of giving informed consent

Exclusion criteria

Exclusion criteria are:
* Any known condition that could limit life expectancy <6 months

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	16-02-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL33779.068.10