Assessment of cardiac resynchronization therapy in patients with wide QRS-complex and non-specific intraventricular conduction delay: a randomized trial.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON54616

Source
ToetsingOnline

Brief title
NICD-CRT Study

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Clermont-Ferrand University Hospital

Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: Cardiac resynchronization therapy, Heart failure, non-specific intraventricular conduction delay, Prolonged QRS duration

Outcome measures

Primary outcome

Composite of 2 clinical endpoints (12 months all-cause deaths and percentage of

hospitalizations for HF at 12 months) combined using an average z-score.

Secondary outcome

Evaluation of efficacy, analysis of:

- 12- month deaths (HF, cardiovascular and all causes deaths),

- Quality-of-life questionnaires at 6 and 12 months:

o Minnesota Living With Heart Failure Questionnaire: MLWHFQ): improvement of at

least 20 points

- Functional capacity at 6 and 12 months:

o NYHA classification reduction >= 1 class,

o 6-minute walk test improvement of at least 10 % in distance,

o Peak oxygen consumption increased by 1.0 ml/kg/min13,

- Percentage of hospitalizations for HF, for cardiovascular reasons and for all

causes at 6 and 12 months,

- Decrease >15% in end-diastolic and/or end-systolic volumes of the left

ventricle at 6 and 12 months.

Study description

Background summary

Several randomized control trials have found1-6, cardiac resynchronization therapy (CRT) to be beneficial in heart failure patients with reduced left ventricular ejection fraction (HFREF) and prolonged QRS duration. The concept of resynchronization is challenged by the observation that for patients with similar QRS duration, the ones with left bundle branch block (LBBB) respond significantly better than the ones with nonspecific intraventricular conduction delay (NICD). Its definition9, 'wide QRS without the appearance of left or right bundle block', corresponds to a definition by default. Nonspecific intraventricular conduction delay (NICD) is observed in a variety of pathologies and results obtained following CRT are evaluated on limited sample sizes, without dedicated randomized studies. Moreover, the observed results can at times be conflicting. The latest international guidelines tend to restrict the indications in this setting and the question arises as to whether to continue to implant heart failure patients with NICD.
The proposed study will be the first randomized prospective assessment of benefit of CRT in HFREF with NICD.

Study objective

To date, no dedicated prospective, randomized, blinded trials have been performed to assess the benefit of CRT in patients with NICD. It is difficult to hypothesize whether CRT implantation may be beneficial in patients with NICD. The objective of the present study is to assess the clinical effectiveness of cardiac resynchronization therapy in HF with reduced ejection fraction patients with NICD on 12-month HF status.

Study design

This is a prospective, controlled, two-parallel arm, randomized, double-blind design and multicentric clinical trial comparing a CRT-D or CRT-P ON group (DDD or VVI biventricular mode, clinicians will define for each patients the best atrioventricular delays) vs. CRT-D or CRT-P OFF group (back-up stimulation mode: VVI 40 bpm) in HF with reduced ejection fraction patients with NICD. The programming of randomization will be introduced after the completion of baseline*s assessment (clinical examination, biological sample, trans-thoracic echocardiography, 6 min walking test, QOL and VO2). Patients who had theses exams performed before implantation, will be randomized directly after and before the discharge. However, patient who didn*t received exams before implantation, will be seen within two weeks from the implantation, for the realization of these tests. In this situation, after implantation, the device is set on OFF and will be activated according to the arm of randomization after

baseline assessment. Remote monitoring will be activated systematically in all included patients before discharge.

Intervention

A pacemaker or defibrillator associated with a CRT system will be implanted according to the standard care procedures. The decision to implant a pacemaker or a defibrillator associated with CRT system will be taken by interventional cardiologist according to guidelines, age of the patient, etiology of the cardiopathy and habits.
The group of 200 patients will be randomly divided into 2 groups: (1) the CRT-ON group: activated CRT system or (2) the CRT-OFF group: inactivated CRT system.

Study burden and risks

The expected benefit of the present study might be an improvement in NYHA class, quality of Life and decrease of HF hospitalizations and mortality.
Patients included in the present are not exposed to specific risk since devices used in CRT implantation are currently used in standard care.

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 over 18 years* old
- NYHA class II to IV ambulatory
- QRS duration > 130 ms
- Patients with sinus rhythm
- LVEF < 35%
- QRS morphology: NICD according to the AHA/ACCF/HRS Recommendations (non-LBBB and non-RBBB):
o Not broad notched or slurred R wave in leads I, aVL, V5 and V6;
o Presence of a Q wave in leads I, V5, V6;
o No rsr*, rsR* or rSR* pattern in leads V1 or V2.
- Life expectancy expected to exceed one year with a good functional status
- Optimal pharmacological therapy of heart failure according to clinician

Exclusion criteria

- Inability to understand nor decline the study,
- Impaired mobility,
- Unable to fill out questionnaire independently,
- Patients with permanent atrial fibrillation,
- Pregnant women,
- Dependant adult,
- Patients minor,
- Life expectancy < 1 year due to other causes than HF.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2019
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Devices used in cardiac resynchronization therapy;standard care
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-05-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-08-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-08-2021
Application type:	Amendment
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
Other	02454439
CCMO	NL65130.068.18