ICONIC-M: IMPROVING CRT OUTCOME WITH NON-INVASIVE CARDIAC MAPPING;A multicentre randomised controlled study to assess patient response to CRT comparing ECGI map guided left ventricular lead placement with empiric lead placement.

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

Summary

ID

NL-OMON53972

Source
ToetsingOnline

Brief title
ICONIC-M

Condition

- Heart failures

Synonym
cardiac arrhythmia, Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: EP Solutions SA
Source(s) of monetary or material Support: EP Solutions SA financiert het onderzoek.

Intervention

Keyword: CRT, ECGI, LVESVI, Response

Outcome measures

Primary outcome

The primary endpoints of this investigation are:

• Left Ventricular End-Systolic Volume index (LVESVi) (mL/m2) mean reduction of additional >=30% (active arm) compared to empiric CRT LV lead implantation (control arm) at 6 months post-implantation versus baseline measured by transthoracic echocardiography.

• The proportion of patients in the ECGI map-guided (active) arm having a distance from the active pole of the LV lead to LV LEAS at 6 months follow-up <= 47 mm being significantly higher than in the non-guided (empiric lead placement) arm (control arm).

Secondary outcome

Secundary endpoints:

• Rate of Amycard 01C associated AEs.

• Rate of correctly predicted distance of venous access within <=47 mm to the LV LEAS using the baseline pre-CRT implant Amycard ECGI map in the Active Arm.

• The degree of LV LEAS shift between baseline and the 6-month follow-up.

• Accuracy of early activation site reconstruction, measured at 6-month follow-up.

Descriptive endpoints, including but not limited to:

• LVESVi (mL/m2) reduction (%) in subjects with LV lead distance <=47 mm from the LV LEAS in the Control Arm compared to the Active Arm at 6 months post-implantation.

• The Clinical Composite Score (CCS) at 6 months post-implantation based on:

o Mortality rate

o HF hospitalization rate

o Patient Global Assessment questionnaire

• The Left Ventricular Ejection Fraction (LVEF) (%) at 6 months post-implantation compared to baseline.

• Actual distance between the LV lead active pole and the LV native rhythm LEAS at 6 months post-implantation

• Non-responder rate at 6 months post-implantation

o Where CRT response is defined as: a decrease in left ventricular (LV) end*systolic volume (LVESV) of >=15% and/or absolute increase of 5% in LVEF (%) at the 6*month visit

• ECGI acquisition procedural failure rate

• ECGI acquisition time

• Total CRT implant time (incision-to-closure time)

• Subgroup analysis based on conditions or habits such as: ischemia vs

non-ischemia, arrhythmias, diabetes, smoking,

renal disease, QRS duration native rhythm, NYHA Class, gender, age,

baseline LVESV, baseline EF, hypertension, pulmonary hypertension,

COPD, impaired RV function, cerebrovascular disease, peripheral

vascular disease, and HF related medication

• The degree of LV LEAS shift between baseline and the 6-month follow-up.

• The practice change effected by ECGI measured by the pre-CRT implant

and post-CRT implant Investigator Questionnaire.

o The proportion of plan changes assessed by comparing the implanters

pre-CRT intended target LV lead location and the actual targeted LV

lead location.

Study description

Background summary

Cardiac Resynchronization Therapy improves cardiac function, symptoms, and well-being, and reduces morbidity and mortality in an appropriately selected group of HF patients. While CRT is an effective therapy, approximately 30% of patients treated with CRT do not respond to the therapy.
Previous clinical data have indicated that the distance between the LV pacing site and site of LV latest electrical activation (LV LEAS) is a strong independent predictor for CRT response. A potential strategy for improving CRT outcome could be to optimize the left ventricular lead placement (LVLP) by using electrocardiographic imaging (ECGI).

Electrocardiographic imaging (ECGI) is a noninvasive mapping and imaging modality for cardiac electrophysiology (EP). ECGI determines noninvasively and with high resolution the electrical activity of the heart from electrical data recorded on the body surface together with cardiac CT images.

ECGI mapping provides valuable information for guiding the CRT lead placement during implantation. The technology may optimize CRT therapy, eventually leading to a better selection of patients for CRT, overall improving the outcome of CRT procedures, resulting in a reduction of the current CRT failure rate.

The main purpose of this study is to assess whether ECGI map-guided left ventricular lead placement (LVLP) improves CRT outcome at 6 months post-implantation in de-novo CRT patients. The ECGI mapping is generated with the CE marked Amycard 01C System.

Study objective

The primary objectives of this investigation are to evaluate whether pre-acquired Amycard ECGI map-guided LV lead placement (I) improves CRT volumetric response compared to non-guided (empiric) LV lead placement, and (II) reduces the distance to LV LEAS compared to non-guided (empiric) lead placement.

Study design

A multicenter randomized controlled study to assess patient response to CRT comparing ECGI map guided left ventricular lead placement with empirical lead placement.

Intervention

For the active arm group:
ECGI mapping (paired with a CT scan) of the heart, prior to CRT implantation and 6 months after CRT implantation.

For the control group:
ECGI mapping (paired with a CT scan) of the heart, 6 months after CRT implantation.

Study burden and risks

Amycard 01C System Related:
Subjects may experience skin irritation when applying the electrodes for perfoprming the ECGI mapping with the Amycard 01C system.

CT-scan related:
The estimated radiation dose of a native CT-thorax (high tube voltage) + heart (Coronary Computed Tomography Angiography (FLASH)) is approximately 4-6mSv for both of these scans in total.
Subjects in the Active group will undergo the CT-scan twice (i.e. 2x 4-6mSv =

8-12mSv), whereas subjects in the Control group will undergo the CT-scan once (i.e. 4-6mSv).
The amount of radiation for this type of CT-scan will be comparable to the amount of natural radiation the patient is exposed to over a 3-year period (i.e. 2-5 mSv a year).

The load and/or risks to which subjects are exposed in this study are considered to be low to negligible.

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

Eligible subjects must meet all of the following criteria to be included in the study:

1. Appropriately signed and dated informed consent.
2. Age >=18 years at time of consent.
3. Considered stabilized after >=3 months of optimal medical therapy before screening
4. Patient in Sinus Rhythm at the time of screening, having LBBB per ESC guidelines 2013.
a. QRS duration >=120ms
b. QS or rS in lead V1
c. Broad (frequently notched or slurred) R waves in leads I, aVL, V5, or V6
d. Absent Q waves in leads V5 and V6
5. Patient is intended for placement of a CRT device with biventricular (BiV) pacing.

Exclusion criteria

Subjects that meet any of the following criteria will be excluded from the study: 1. Currently implanted with pacemaker or ICD with >20% RV pacing in the past 3 months. 2. Acute diseases or exacerbations of chronic diseases (as per the investigator*s discretion) 3. Contraindications to CT-scanning 4. Contraindications to body surface ECG mapping: o ongoing wound healing on the chest (e.g. recent surgery) o skin diseases o allergic reactions to surface mapping electrodes and medical band-aid 5. Pregnant, or subjects planning to become pregnant within 24 months after signing informed consent o A documented negative pregnancy test (serum or blood) is required for women of childbearing potential. 6. Incapacitated individuals, defined as persons who are mentally ill, mentally handicapped, or individuals without legal authority, are excluded from the study population

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-12-2023
Enrollment:	186
Type:	Actual

Medical products/devices used

Generic name:	Amycard 01C
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-08-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-06-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT05564793
CCMO	NL82710.100.23