Multicenter post-market study to assess and im-prove patient response to CRT therapy with the amy-card 01C system(MAP-CRT)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON55303

Source
ToetsingOnline

Brief title
CRT study with amycard 01C stystem

Condition

- Cardiac arrhythmias

Synonym
CRT device; heart rhythm failure

Research involving
Human

Sponsors and support

Primary sponsor: EP Solutions SA

Source(s) of monetary or material Support: EP Solutions SA

Intervention

Keyword: Amycard 01C system, CRT Therapy

Outcome measures

Primary outcome

Primary endpoint is the LVESV, assessed by echo examination at 6-12 months post CRT implan-tation. The cut-off parameter for response/non-response is LVESV reduction of 15% or more versus baseline.

LV size should be assessed on a 2D echo examination by calculating volumes using the biplane method of disks summation technique. In sites and operators with experience in 3D echo, 3D measurement and reporting of LV volumes is recommended when feasible depending on image quality, see further details in the recommendations of the American Society of Echocardiog-raphy and the European Association of Cardiovascular Imaging (#23 in the reference list).

Secondary outcome

Secondary endpoint is a composite clinical score of death and HF hospitalization at 12 months
post-implantation.

Note:

The LVESV parameter will assess patient improvement at the 6-12 months follow-up-visit. However, to accommodate variance in the timing of the follow-up-visit, deaths and HF hospitalizations will be taken into account

until 12 months after the implantation.

Study description

Background summary

The use of ECGI in current electrocardiography practice aims at reconstructing epicardial and endocardial electrical signals from the heart in order to detect disorders in the cardiac electri-cal system. The Amycard 01C System (previously called EPCard IVM) has been technically and clinically validated, which also formed the basis for the acquired CE certification of the system.
The question which was the basis for validating with regard to the system performance was the capability of the Amycard 01C System to accurately generate epicardial and endocardial maps of the cardiac electrical activity and, further, to detect ectopic events for their use in the diag-nostic process. The evaluation of the performance relies on a series of 8 clinical studies carried out with the Amycard 01C System on a total of 118 patients as well as on clinical studies pub-lished on an equivalent device.
All studies conducted on the Amycard 01C System concur to establish the clinical utility of the system as a tool for the non-invasive study of various cardiac diseases that would otherwise require an invasive electrophysiological study. Both clinical validation data and data collected from Post Market Studies (PMS) indicate that the Amycard 01C System is safe and performant when used with either CT or MRI imaging modalities. The studies confirm the suitability of non-invasive mapping.

Study objective

We hypothesize that a noninvasive ECGI mapping-based system, like the Amycard 01C system, can provide information valuable for both selecting patients for CRT therapy, planning the CRT procedure, guiding the actual CRT lead placement during implantation as well as optimizing the CRT therapy, leading to a better selection of patients for CRT and an overall improved outcome of the procedure and thus reducing the current 20-50% procedure failure rate.

Based on the above hypothesis we foresee a long-term clinical roadmap that can be divided into the following sub-studies:

1. Demonstrate that the non-invasive ECGI mapping can predict CRT response * retrospec-tive study in patients undergone CRT implantation.
2. Demonstrate that prospective use of ECGI map to guide LV electrode placement by as-sessing the LV Late Activation Zone (LAZ) in relation to CT venography provides better CRT outcome (prospective randomised controlled study).

3. Demonstrate that pre-procedure assessment of the LAZ vs CT venogram and Q-LV and RV-LV activation time from ECGI map can predict
CRT response pre-procedure * thus can be used to screen and select
patients (prospective randomised controlled study).

The current study will support objective 1) above, and is based on the fact that the distance be-tween the CRT LV pacing pole and the LV native Late Activation Zone has previously been shown to correlate to response or non-response to CRT. We hypothesize that the Amycard 01C surface ECG mapping system in combination with CT imaging can be used to non-invasively identify the native LV Late Activation zone and its distance to the CRT LV pacing pole, and by applying this method in a cohort of patients previously implanted with a CRT device demon-strate that the Amycard 01C System is being able to predict non-response to CRT.

The objective of the study is to establish on a statistically significant number of samples wheth-er the distance between the Late Activation Zone (LAZ), as identified non-invasively with the Amycard 01C System, and the location of the LV pacing pole is a predictor of CRT procedure outcome.

Study design

Study Type
Prospective Blinded Multicenter Post-Market Non-Invasive Study assessing lead placement and native ventricular activation in responding and non-responding CRT patients.
5.2 Study Sample Size and Study Duration
The investigation will be initiated in Europe and Russia and will utilize approximately study 6 sites. The goal of the study is to enroll 150 patients across several sites in the months of November 2020 to June 2021.

Study burden and risks

Risks Associated with the Study Device System
Clinical data from published literature of equivalent devices to the Amycard 01C System, which are certified and are currently placed on the market, have been evaluated and appraised for clinical safety and performance data. Therefore, there are no known anticipated AE*s which could be directly related to the study device or similar CE labelled devices currently available.
Risk-Benefits Analysis
The use of the non-invasive mapping-based CRT protocol using the Amycard 01C System is in-tended for the acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

It has been judged that the current risk management documentation is consistent with the clini-cal data presented in the accompanying literature review and

adverse event database search, and that all hazards have been adequately covered.
Post-market surveillance data obtained from 16 sites where the Amycard 01C System has been installed and used on a total of 595 patients shows no complaints or adverse events.

No adverse events related to Amycard 01C System or its equivalent devices were found in any of the consulted databases. There are no reports of safety-related issues or side-effects in clini-cal literature relevant to the Amycard 01C System or its equivalent devices.
Possible risk aasociated with having a CT-scan include but are limited to. Risk of CT-scan allergic reaction to the contract, side effects to the contracts: diarrhea, headache, and dizziness. Anxiety, claustrophobia, nephropathy and radioation exposure.
The amount of radiation for this type of CT scan is below the amount of natural radiation the patient is exposed to over a 3-year period. The risk of radiation exposure from a CT might in-crease the risk of cancer to 1 in 2000.

That non-invasive mapping can potentially substitute invasive mapping to assist the electrophysiologist in the diagnostic process, indicates that both the device and its study related application have an un-doubtedly positive risk-benefit profile. They would not cause an electrophysiologist to make a different diagnosis nor abnormal treatment planning than if the traditional methods were used.

Considering all available information, the Amycard 01C System does not compromise the safety of patients, users or other persons, when used under the conditions and for the purpose
intended.

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

1. Appropriately signed and dated informed consent.
2. Age *18 years at time of consent.
3. The presence of a CRT device implanted 6-24 months ago.
4. Patients in Sinus Rhythm or AF with BiV pacing >90%.
5. Patients that fulfilled Class I or Class IIa clinical recommendations per the ESC Guidelines at the time of implantation.
6. Patients have correctly set pacing parameters (interventricular delay) according to the ESC Guidelines (QRS duration, Echo).
7. Patients were reliably diagnosed with the cause of heart failure.
8. Patients had a reliable assessment of the degree of cardiac failure before CRT device implantation and during the follow up period.

Exclusion criteria

1. Patients with acute diseases or exacerbations of chronic diseases; recent surgery.
2. Patients who have contraindications to CT scanning: excess body weight (BMI >40)
recent x-ray examination (CT, interventional procedures under fluoros-copic control), radiation therapy, allergic reactions to iodine, intolerance
to X-ray contrast agents, kidney diseases with elevated creatinine levels, (>45)
diseases of the thyroid gland with impaired T3 and T4 levels, difficulties for venous access, blood clotting disorders.
3. Contraindications to body surface ECG mapping: recent surgery on the chest, skin diseases, allergic reactions to surface mapping electrodes and

medical band-aid.
4. Patients that have undergone AV nodal ablation and/or are pacemaker dependent.
5. Pregnant, nursing or planning to become pregnant (documented negative pregnancy test required documented within a maximum of 7 days prior to procedure for all women of childbearing potential. Documentation of effective contraception is also required for women of childbearing potential).

Study design

Design

Study type: Observational invasive

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2021
Enrollment:	38
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	26-04-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	20-01-2022
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
CCMO	NL75071.068.20