Advanced Image Supported Lef ventricular Lead Placement in Cardiac Resynchronization Therapy

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Primary Objective: -To test the feasibility of MRI and CT fusion with 3D rotational venogram / fluoroscopy for left ventricular lead positioning in CRT.Secondary Objectives: -Visualize the location and distance to LV lead position of MRI determined...

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

Summary

ID

NL-OMON44064

Source
ToetsingOnline

Brief title
Advise-CRT

Condition

- Heart failures

Synonym
cardiac decompensation, chronic heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Octopus grant divisie Hart & Longen

Intervention

Keyword: 3D venogram, Cardiac Resynchronisation Therapy, Left ventricular lead, MRI

Outcome measures

Primary outcome

Feasibility

- Quality of MRI;

- Quality of CT;

- Quality of treatment file (CARTBox3);

- Quality of 3D venogram;

- Fusion feasibility;

- Fluoroscopy time;

- Contrast dose CT;

- Radiation dose CT;

- Radiation dose of CRT implantation;

- Complications during CRT implantation;

- Implantation duration.;

- Patient repositioning;

- Number of additional 3D images.

Secondary outcome

LV lead parameters (recorded of each possible position).

-Lead/electrode position in RAO 30° en LAO 40° view;

-Lead/electrode position in 3D view;

-Distance of lead/electrode to infarct location;

-Distance of lead/electrode to phrenic nerve position;

-Distance of lead/electrode to latest activated segment;

-Pacing and n. phrenicus threshold;

-Type of LV lead;

-QLVsense (of each electrode);

Study description

Background summary

Chronic heart failure is a major cause of morbidity and mortality in the Netherlands, with a prevalence of 6.2 per 1000 in men and 8.5 per 1000 in women. In 2010, 29.838 patients were hospitalized due to clinical heart failure and the death of 6.424 patients was reported as a consequence of heart failure. Heart failure accompanied by ventricular dyssynchrony, determined by a wide QRS complex on het electrocardiogram (ECG), is a predictor for worse prognosis. A wide QRS complex (>120ms) is present in about 25-50% of patients with chronic heart failure.

According to the most recent guidelines, patients with a wide QRS complex are found to benefit from pharmacological therapy accompanied by general advice concerning diet, weight, smoking and exercise. Patients who remain in NYHA class II or higher despite pharmacological therapy, with a left ventricular ejection fraction of <35%, are found to benefit from cardiac resynchronization therapy (CRT). There is a class I level of evidence with a level *A* indication for CRT in recent guidelines, to reduce morbidity and mortality.

The rationale for CRT is based upon the observation that the presence of ventricular dyssynchrony (a wide QRS complex) can induce systolic dysfunction and thereby worsen heart failure. To correct ventricular dyssynchrony, three pacing leads are implanted via a transvenous approach and connected to the CRT device. One electrode is positioned in the right atrial appendage or interatrial septum, another electrode in the right ventricular (RV) apex and a third electrode in a venous branch of the coronary sinus, pacing the LV epicardium. These ventricular leads pace the LV at two contralateral sites, reducing dyssynchrony. Unfortunately up to 30-45% of patients do not benefit from CRT. These patients either stabilize or progress in heart failure. The effectiveness of CRT is subject to a varied amount of factors, such as patient selection, device programming and LV lead placement. The latter is of major importance. A MADIT-CRT substudy showed that pacing at a more distal and/or apical position was a common finding in patients not responding to CRT. As we have found in the first OPTICARE study, optimization of device settings cannot

overcome a suboptimal lead position. Moreover, lead placement in a targeted area of latest mechanical contraction and away from myocardial infarction, determined by speckle tracking echocardiography, improves response and prognosis. Multiple studies have advocated the adverse effects of pacing in or near an area of myocardial infarction. Lead placement is therefore an important factor in CRT implantation. LV lead placement is however restricted by venous anatomy, lead stability (e.g. need for wedging), local pacing parameters, fibrosis and/or infarct location, and phrenic nerve involvement. Determining the optimal position can therefore be difficult.

Improving LV lead position during implantation, is therefore of importance. Currently, the optimal lead position is based on the preference of the cardiologist. The implanting physician has restricted information on the optimal position. Pre-implantation knowledge of infarct location, combined with pacing and phrenic nerve thresholds and the visualized coronary venous anatomy give a limited insight in possibilities and restrictions. Based on avoiding known predictors, as an apical position, estimated infarct location and phrenic nerve thresholds during stimulation, the lead is placed in a suitable vein.

Information on infarct location, latest contracting area, and phrenic nerve position in relation to cardiac venous anatomy, before and during implantation, could improve the final LV lead position. MRI can provide all these aspects, fused with a 3D rotational venogram and fluoroscopy images during implantation. MRI with delayed enhancement imaging can provide information on infarct location, size and transmurality. MRI-tagging can give information on myocardial deformation and thereby the latest contracting area. Lastly, location of the phrenic nerve can be imaged by detailed MRI imaging with tissue characterization. Reconstruction of the information provided by MRI can give the implanting physician a detailed overview, for clinical decision making. Moreover, by real time fusion of 3D reconstruction of MRI with a rotational venogam by fluoroscopy during implantation, the implanting physician can determine the optimal lead position. After imaging cardiac venous anatomy, the cardiologist can choose which side branch of the coronary sinus is ideal for LV lead placement.

Software for fusion of MRI and CT with a 3D rotational venogram is currently developed by CART-Tech (CART-Tech B.V., Utrecht, the Netherlands). The dedicated software package (CARTBox 3) of this spin-off scientific company of the UMC Utrecht will be used for the study. Its features will be continuously developed during the study. Specific additions for phrenic nerve visualization by CT and myocardial deformation results of MRI-tagging will be made during the study and tested in subgroups. A final software package will be used in a small population to test the feasibility of CARTbox for CRT implantation purposes.

Study objective

Primary Objective:

-To test the feasibility of MRI and CT fusion with 3D rotational venogram / fluoroscopy for left ventricular lead positioning in CRT.

Secondary Objectives:
-Visualize the location and distance to LV lead position of MRI determined scar tissue combined with 3D rotational venogram / fluoroscopy images during CRT implantation.
-Visualization and location of the left phrenic nerve, by MRI fusion with 3D rotational venogram / fluoroscopy, in relation to cardiac anatomy and LV lead position.
-Determine the latest contracting region by MRI-tagging analysis and applicability in LV lead positioning, by MRI fusion with 3D rotational venogram / fluoroscopy.

Study design

The ADVISE-CRT study is an observational pilot study. The feasibility of magnetic resonance imaging (MRI) and computed tomography (CT) based left ventricular lead positioning in CRT is evaluated. As experience needs to be gained and data needs to be gathered, a step-wise approach will be implemented. Steps will be used to test specific features of MRI and CT fusion with fluoroscopy images during implantation. An additional aspect of MRI or CT imaging will be added at each step. Every step will be executed in three patients The fusion of myocardial scarring, detected with MRI by delayed enhancement imaging, with fluoroscopy will be the first step (MRI). The second step will be incorporation of MRI-tagging with detection of the latest contracting segment (MRI). The third step will incorporate visualization of the phrenic nerve (CT). A final review group of 6 patients will be the last step, in which the LV lead position will be decided based on the MRI fused images.

Intervention

In the final review group of 6 patients, the cardiologist will use the 3D venogram and fused MRI and CT images during CRT implantation, to optimize the LV lead position.

Study burden and risks

The risk and/or complications of the CRT-D implantation itself are not additional to the study, as the CRT-D implantation with a quadripolar lead is a standard procedure in the UMC Utrecht.

During implantation an 3D venogram is made, which replaces commonly made 2D fluoroscopy images. There may be a slightly increased radiation and/or contrast burden. However, the effects of the relatively small increase will be negligible.

The MRI scan is standard care in patients planned for CRT implantation. The additional images prolong the scan duration and therefore cause a minor burden. The CT scan implemented in the last two phases causes an increased risk due to radiation and contrast.The burden of these risks is small.

The study can ameliorate the response of patients to CRT. By fusing MRI and/or CT images with fluoroscopy during LV lead positioning, the implanting physician can choose a position which would benefit LV function. A lead position with away from the infarct area, away from phrenic nerve involvement and closest to or in the latest activated area will improve LV pump function. An improved response to CRT can improve quality of life and prognosis of heart failure patients. Especially patients with myocardial infarction and/or coronary artery stenosis (ischemic cardiomyopathy. As these patients are more often non-responders to CRT.

The study may also improve the procedure itself. With increased knowledge of an optimal lead position during implantation, future procedures can be conducted more easily. The implanting physician can choose a target vessel for optimal lead position. It can therefore shorten the procedure and prevent potential complications of prolonged procedures.

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

An indication Cardiac Resynchronization Therapy according to the current international evidence based guidelines for CRT (the 2013 European Society of Cardiology Guidelines for cardiac pacing and cardiac resynchronization therapy):
-Chronic heart failure;
-New York Heart Association functional class II, III, IV (ambulatory);
-QRS duration *120ms;
-Optimal pharmacological therapy;
-Left ventricular ejection fraction *35%;;And specifically for phase 1 of the study:
-Documented history of myocardial infarction, coronary artery disease, or delayed enhancement on a prior MRI.

Exclusion criteria

-Contraindications for implantation of a CRT device;
-Age <18 years or incapacitated adult;
-Pregnancy; if there is anamnestic doubt regarding postmenopausal state (<1 year since last menstruation), an urine hCG test (Alere) will be performed.
-Lactation;
-Impaired renal function (severe renal insufficiency, GFR < 30 ml/min/1.73m2);
-Permanent atrial fibrillation or atrial fibrillation during MRI
-Documented allergic reaction to gadolinium;
-Documented allergic reaction to contrast agent;
-Impossibility to undergo a MRI scan (determined by using the standard contraindications for MR imaging as used for clinical purposes).
-Participation in another clinical study that prohibits any procedures other than standard.
;After study MRI:
- No delayed enhancement on MRI

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	CARTBox3
Registration:	No

Ethics review

Approved WMO

Date:	08-06-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL54635.041.15