Optimization of Cardiac Resynchronization Therapy with a Quadripolar Left Ventricular Lead

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The primary objective of the study is to determine whether the intrinsic electrical delay (QLVs) at a specific pacing site is correlated to acute hemodynamic response (by percentage increase in strokework, %SW) in CRT with a quadripolar lead.

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

Summary

ID

NL-OMON44474

Source
ToetsingOnline

Brief title
OPTICARE-QLV

Condition

- Heart failures
- Cardiac therapeutic procedures

Synonym
Chronic heart failure, decompensation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Eigen middelen

Intervention

Keyword: Cardiac resynchronization therapy (CRT), Optimization, QLVs, Quadripolar lead

Outcome measures

Primary outcome

The electrical delay at the quadripolar electrodes (expressed as QLVs) and its correlation with the acute hemodynamic response (expressed as %strokework).

Secondary outcome

The difference in acute hemodynamic benefit (strokework (%SW) and %dP/dt) between pacing with the optimal configuration of a quadripolar LV lead and multi point pacing, as compared to conventional biventricular pacing.

Electrophysiological measurements of the LV electrodes (phrenic nerve stimulation, pacing threshold, sensing amplitude, impedance, RVP-LVS, LVP-RVS, LV1P-LV2S and LV2P-LV1S intervals

Myocardial strain (derived by MRI), combined with pressure (derived from PV-loops) into pressure-strain loops to quantify myocardial (wasted) work.

Quantifying reverse remodeling by measuring echocardiographic biplane (four-chamber and two-chamber view) end systolic volume (ESV). Reverse remodelingi is expressed as the percentage change in ESV between baseline and 6 months.

QRS-duration and beat-to-beat variability of repolarization (BVR) by

electrocardiogram (ECG).

Study description

Background summary

Chronic heart failure is a major cause of morbidity and mortality in the Netherlands. 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, optimal pharmacological therapy, New York Heart Association (NYHA) functional class II-IV/IV and a left ventricular (LV) 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% of patients do not benefit from CRT. The effectiveness of CRT is subject to a varied amount of factors, such as patient selection, device programming and LV lead placement. As we have found by the first OPTICARE study, the effect of CRT can be optimized by programming the atrioventricular delay (AVD) and interventricular delay (VVD), resulting in an improved systolic function expressed by dP/dt. Optimizing the AVD and VVD can thus improve the hemodynamic effect of CRT, however optimization of these delays cannot overcome a suboptimal lead position. 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. Lead placement is therefore an important factor in CRT implantation. LV lead placement is restricted by venous anatomy, lead stability (e.g. need for wedging), local pacing parameters and phrenic nerve involvement. The recently developed quadripolar lead has the ability to pace at four electrodes spaced 47mm apart. The three extra electrodes can overcome suboptimal conditions at the most distal electrode, the latter being the pace site of conventional bipolar LV leads. A quadripolar lead can therefore improve response to CRT.

Finding the optimal site of LV stimulation is a interesting and developing

research field. Novel parameters, depicted from interelectrode delays are of interest, as the values found directly correlate to lead position. The QLVs is such a parameter and has shown potential to predict acute hemodynamic response in several studies. Pacing at a long QLVs (>95) even predicts a favourable prognosis. This study aims to correlate the QLVs of the four electrodes of a quadripolair lead to acute hemodynamic response with pressure-volume loops. So that QLVs can be used as a lead positioning target for future implantations.

Study objective

The primary objective of the study is to determine whether the intrinsic electrical delay (QLVs) at a specific pacing site is correlated to acute hemodynamic response (by percentage increase in strokework, %SW) in CRT with a quadripolar lead.

Study design

Prospective single centre observational study with invasive measurements, implemented after CRT implantation.

Moreover, MRI images will be obtained before the procedure for calculation of strain. Myocardial wasted work, derived from pressure-strain curves of optimal configuration (biventriculair, quadripolar and MPP), is compared to intrinsic rhytm.

During the CRT implantation procedure, the optimal lead position and pacing vector of the quadripolar LV lead are determined. The correlation of the electrical delay at the electrodes (QLVs) and the hemodynamic benefit will be determined. Invasive measurement of LV pressure and intracavitary volume (pressure-volume loops) is used. Optimal settings are compared to standard biventricular (BiV) pacing and to multi point pacing (MPP).

Finally, the beat-to-beat variability of the repolarization (BVR) is determined by alternating the atrioventricular delay.

Study burden and risks

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

The PV conductance catheter will be inserted as described above. Femoral arterial access is a routinely used procedure in the UMC Utrecht department of cardiology and has been routine practice in the electrophysiological laboratory. The use of the catheter has known complications. Possible intraprocedural complications due to insertion of the catheter are cardiac

arrhythmias, which are directly recognized by ECG monitoring and effectively treated by retracting the catheter or defibrillation. Other, very rare, but potentially life threatening and/or irrreversibal intra-procedural complications can occur. Possible intraprocedural complications such as are cardiac tamponade (treated with a pericardial drain), cerebral vascular incidents (incidence 0.09%) or coronary artery dissection. However rare (incidence 0.7 - 2.7%), postoperative complications of arterial catheterization (e.g. local bleedings and pseudo-aneurysms) are seen. These complications are not life threatening, are easily recognized by treating nurses or physicians and can be treated effectively, without permanent damage. Pseudo-aneurysms are treated with trombone injection, bleedings with pressure on the wound or operative closure if persistent. Patients are restricted to bed rest for a period of 90 minutes, after closure of the arterial access with an Angioseal.

Measurement of BVR during alternation of the AV interval will not lead to a direct benefit to the patient. However, these measurements will add a maximum of only 5 minutes and cause no harm to the subjects* health.

Strain analysis with MRI will lead to a better understanding of hemodynamic en mechanical interaction of CRT. Transthoracic echocardiography is a non-invasive and safe diagnostic tool, and will not cause any risk for the subjects.
However, these measurements will not lead to a direct benefit to the patient.

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 with an indication for 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;
- Left bundle branch block
- Optimal pharmacological therapy;
- Left ventricular ejection fraction *35%.

Exclusion criteria

- Contraindications for implantation of a CRT device;
- Age <18 years or incapacitated adult;
- Pregnancy (clarified in E5);
- Severe aortic valve stenosis with a valve area <1,0 cm2 or aortic valve replacement in history;
- Participation in another clinical study that prohibits any procedures other than standard.
- Permanent atrial fibrillation or atrial fibrillation during CRT implantation;The exclusion criteria regarding the MRI are:
- Lactation;
- Documented allergic reaction to gadolinium;
- Subjects with impaired renal function (severe renal insufficiency, GFR < 30 ml/min/1.73m2);
- Impossibility to undergo a MRI scan (determined by using the standard contraindications for MR imaging as used for clinical purposes).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	16-07-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-04-2016
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	NL48172.041.14