# Advanced Image Supported Lead Placement in Cardiac Resynchronization Therapy: feasibility in a multicentre setting

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23393

**Source**
NTR

**Brief title**
ADVISE

**Health condition**

Chronic heart failure with a reduced ejection fraction and dyssynchrony

### Sponsors and support

**Primary sponsor:** University Medical Center Utrecht
**Source(s) of monetary or material Support:** UMC Utrecht

### Intervention

### Outcome measures

**Primary outcome**

Feasibility as assessed by the following feasibility criteria:

- Time to perform the placement of the LV lead
- Overall CRT implantation procedure duration
- Number of LV lead repositioning procedures.

Validation of the accuracy of 2D image registration compared to standard 3D image registration (in five patients).
- Procedural efficiency scored by the implanting cardiologist

### Secondary outcome

Safety:
- Radiation dose during the procedure
- (Serious) adverse events

Efficacy:
- Relative reduction in left ventricle end-systolic volume (LVESV), at 6-month follow-up.
- Proportion of volumetric responders (≥ 15% reduction in LVESV), at 6-month follow-up.
- Reduction in log-transformed NT-proBNP, at 2-month follow-up.

## Study description

### Background summary

Cardiac resynchronization therapy (CRT) is an established pacemaker therapy for patients with symptomatic chronic heart failure, but is hampered by a non-response rate of 30-40%. Optimising left ventricular lead placement is the cornerstone of improving treatment. The optimal location for the lead is remote from scar but within segments demonstrating late electromechanical activation. The present study aims to investigate the feasibility of the use of real-time guided lead placement using cardiac MRI and fluroscopy in a multicentre setting.

### Study objective

1. Targeted LV-lead delivery is safe and feasible in a multicenter setting.
2. Image-registration using 2D fluroscopy is non-inferior compared to standard 3D image registration (validation in first five patients).
3. Targeted LV-lead delivery will increase the proportion of responders, as compared to historic percentage of responders (60-70%).

### Study design

Timepoint 1: Pre-implantation CMR and echocardiography
Timepoint 2: Guided CRT implantation

### Intervention

Real-time cardiac Magnetic Resonance-guided lead implantation by CARTBox.

# Contacts

**Public**
UMC Utrecht
Philippe Wouters

+31 88 75 743 75
**Scientific**
UMC Utrecht
Philippe Wouters

+31 88 75 743 75

# Eligibility criteria

## Inclusion criteria

Capacitated adult patients referred for CRT with a class 1 or 2a indication for CRT according to the 2016 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure.

## Exclusion criteria

Contraindications for implantation of a CRT device;
- Age <18 years or incapacitated adult;
- Pregnancy or lactation
- Subjects with impaired renal function (severe renal insufficiency, GFR < 30 ml/min/1.73m2);
- Atrial fibrillation or atrial fibrillation during MRI
- Documented allergic reaction to gadolinium or contrast agent;
- Impossibility to undergo an MRI scan
- Participation in another clinical study that prohibits any procedures other than standard.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 12-09-2019 |
| Enrollment: | 30 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 03-04-2020 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 49313
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL8506 |
| CCMO | NL67885.041.19 |
| OMON | NL-OMON49313 |

# Study results

**Summary results**

For previous work, please see Salden OAE et al. Multimodality imaging for real-time image-guided left ventricular lead placement during cardiac resynchronization therapy implantations. 2019. Int J Cardiovasc Imaging. 2019 Jul;35(7):1327-1337.