# Pacing In Cardiac Magnetic Resonance Imaging: a CRT trial

No registrations found.

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

## Summary

### ID

NL-OMON24342

**Source**
Nationaal Trial Register

**Brief title**
PICARIA-CRT

**Health condition**

Heart failure

### Sponsors and support

**Primary sponsor:** Biotronik Nederland b.v.
**Source(s) of monetary or material Support:** Biotronik Financial Support

### Intervention

### Outcome measures

**Primary outcome**

The primary objective of this pilot study is to assess the feasibility of CMR imaging in patients implanted with a CMR compatible CRT-D. This includes assessment of both image quality and the accuracy of LV volumetric and functional measurements with and without biventricular stimulation.

### Secondary outcome

- Comparison of additional quantitative CMR parameters post- versus pre-implantation.
- Comparison of quantitative CMR parameters during conventional CRT on versus CRT off. - Relation between baseline dyssynchrony, dyscoordination and (wasted) myocardial work, their changes in response to CRT and acute pump function improvement.

## Study description

### Background summary

10 CRT-D patients will receive a MRI scan and invasive pressure-volume-loop measurements 6 weeks after their CRT-D implantation

### Study objective

CMR imaging is feasible and accurate to measure LV volumes and function in patients implanted with a CMR compatible CRT-D, with and without biventricular stimulation.

### Study design

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### Intervention

Patient will receive a cardiovascular MRI scan and invasive pressure-vollume measurements using a conductance catheter 6 weeks after their CRT-D implantation

## Contacts

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# Eligibility criteria

## Inclusion criteria

Patients need to fulfil the 2013 guideline of the European Society of Cardiology criteria for cardiac pacing and cardiac resynchronisation therapy. In order to participate in this study, a subject must meet all of the following criteria:
- Chronic heart failure
- New York Heart Association (NYHA) functional class II, III or ambulant IV
- QRS duration ≥ 120ms
- Left bundle branch block
- Optimal pharmacological therapy
- LV ejection fraction ≤ 35%
- Sinus rhythm

## Exclusion criteria

The exclusion criteria for this study are:
- Age <18 or incapacitated adult
- Significant rhythm abnormalities (atrial fibrillation or frequent extrasystole)
- Artificial heart valves
- Pacemaker dependency
- Lactation
- Documented allergic reaction to gadolinium
- Subjects with severely impaired renal function ( 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: | Interventional |
| Intervention model: | Other |
| Allocation: | N/A: single arm study |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 20-02-2019 |
| Enrollment: | 10 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 25-06-2019 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL7843 |
| Other | METC VUMC : 2016.032 |

## Study results