

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

NTR

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-volume 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 $\geq 120\text{ms}$
- Left bundle branch block
- Optimal pharmacological therapy
- LV ejection fraction $\leq 35\%$
- 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 ($\text{GFR} < 30 \text{ ml/min/1.73m}^2$)
- 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:	Non controlled trial
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