SONR-ECHO: Clinical Assessment of the SonR Algorithm in the PARADYM RF SonR CRT-D by Echocardiography

Published: 11-09-2014
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Objective of the study is to demonstrate that CRT parameter optimisation using SonR technology can improve the responder rate, when using LV remodeling as a reference, compared to Standard of Care.

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

Summary

ID

NL-OMON40954

Source
ToetsingOnline

Brief title
SONR-ECHO

Condition

- Heart failures

Synonym
heart failure, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Sorin Group Nederland N.V.
Source(s) of monetary or material Support: Sorin Group

Intervention

Keyword: CRT responders, echocardiography, LV remodeling, SonR

Outcome measures

Primary outcome

Left ventricular end-systolic volume

Left ventricular filling time

Secondary outcome

A-wave truncation

Left ventricular end-diastolic volume

Left ventricular ejection fraction

Incidence of atrial fibrillation

Adverse events

Study description

Background summary

Cardiac resynchronisation is an established therapy for patients with heart failure presenting with a wide QRS and ventricular dyssynchrony. However, not all patients are responders to the therapy. Since the introduction of CRT on a large scale, it has been observed that approximately 30-40% of recipient patients are non-responsive to the therapy. The number of non-responders can be diminished by optimal device programming using SonR technology, especially wher the AV and VV interval is concerned (CLEAR study). There are no data available comparing LV remodeling in patients with SonR optimisation as opposed to Standard of Care.

Study objective

Objective of the study is to demonstrate that CRT parameter optimisation using SonR technology can improve the responder rate, when using LV remodeling as a reference, compared to Standard of Care.

Study design

This is an international, multi-centre, 1:1 randomised, two-arm, double-blind prospective study.

Intervention

All patients will undergo, at enrolment and after 6 months, an echocardiographic evaluation of the heart.

Study burden and risks

No additional risk

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

- indication for a CRT-D implant
- in sinus rhythm
- signed informed consent

Exclusion criteria

- previous implant of a resynchronisation device
- persistent atrial arrhythmias
- ventricular tachy-arrhythmias secondary to reversible causes
- incessant ventricular tachy-arrhythmias
- unstable angina, acute myocardial infarction, coronary artery bypass graft, percutaneous transluminal coronary angioplasty in the last 4 weeks
- correctable valvular disease as a primary cause for heart failure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	CRT defibrillator;leads;software

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-09-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL49508.028.14