Clinical Trial of the SonRtip Lead and Automatic AV-VV Optimization Algorithm in the PARADYM RF SonR CRT-D

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

Summary

ID

NL-OMON43949

Source
ToetsingOnline

Brief title
RESPOND CRT Study

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AV-VV optimization, CRT-D, SonR

Outcome measures

Primary outcome

The primary endpoint: the proportion of responders at the 12-month follow-up visit. For the primary effectiveness endpoint, the investigational and control groups will be compared in a non-inferiority context employing a clinically meaningful difference of 10%.

Secondary outcome

This secondary endpoint: de proportion of SonRtip lead-related complication-free rate, defined as the proportion of patients not experiencing any complication related to the SonRtip lead, relative to the total number of patients implanted with the lead.

Study description

Background summary

Since the introduction of cardiac resynchronization therapy (CRT) on a large scale, it has been observed that approximately 30% of recipient patients are non-responsive to therapy This non-responsiveness can be decreased by optimizing the device programming, particularly the stimulation rate, paced and sensed atrioventricular (AV) delay, and the interventricular (VV) delay.

All CRT patients need a 100% rate of ventricular capture, but beyond this the achievement of therapy effectiveness requires the identification of the optimal pacing configuration, which varies among patients. The optimization of CRT systems, usually based on ultrasound imaging,is time-consuming and the number of patients in need of multiple optimization procedures due to ventricular remodeling is growing rapidly.

The mechanical effects of a more coordinated contraction result in a shortening

of the isovolumetric contraction phase and the pre-ejection time, and an increase in LV dP/dt (change in left ventricular pressure over time. The concept of measuring contractility with an implantable accelerometer was first clinically validated through a multicenter study on a rate responsive pacing system (BEST - Living from SORIN Biomedica) in 1996. This study positively demonstrates that measurement of Peak Endocardial Acceleration signal (called PEA or SonR) is feasible and reliable in the long-term, both for the purpose of rate response and as a hemodynamic monitor of cardiac function.

More recent clinical studies have demonstrated that optimal VV and AV Delays determined using algorithms based on SonR signal analysis (SonR method) are correlated with the highest hemodynamic improvement and lead to significant clinical benefit for the patients, thus reducing the rate of non-responsiveness to CRT therapy. These encouraging observations warrant further studies of the SonR sensor on a larger scale, using CRT-D devices and long term follow-up. Therefore, automatic AV and VV delay optimization in patients with CRT devices could benefit both the patient and physician.

Study objective

The objective of this study is to assess the safety and effectiveness of the automatic atrioventricular (AV) delay and interventricular (VV) delay optimization algorithm used in the PARADYM RF SONR Cardiac Resynchronization Therapy with Defibrillation (CRT-D) device (Model 9770) in combination with the SonRtip Lead, which includes a SonR sensor in the tip of the atrial pacing lead, and compatible SmartView programming software.

This study will evaluate the effectiveness of the automatic optimization algorithm in increasing the rate of patients responding to the therapy as compared to an echocardiographic optimization method. This study will also evaluate the safety and effectiveness of the SonRtip atrial pacing lead.

Study design

This is a multi-center, randomized, two-arm, double-blinded, prospective trial. Five-hundred-eighty-two (1032) patients will be enrolled at European and North American investigational sites.

Intervention

After successful implant, the patients will be assigned to either the treatment or control arms, employing a 2:1 randomization with up to 688 patients in the Study Group (SonR CRT Optimization programmed *AV+VV*) and up to 344 patients in the Control Group (echocardiographic optimization; SonR CRT Optimization programmed *OFF*).

Study burden and risks

The burden for the patient will be 30 minutes extra at each visit. There are no predictable increased risks or disadvantages for the patient by participation in the trial due to the implanted system or due to the trial compared to other resynchronization therapies available at the moment.

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

- Patient with a class I and IIa indication for implantation of a CRT-D device according to current available guidelines
- Moderate/severe HF (NYHA class III or ambulatory IV)

- LVEF <= 35%
- LBBB: QRS >= 120 ms; non-LBBB: QRS >= 150 ms
- On stable, optimal durg regimen
- Patient is in sinus rhythm
- Signed and dated informed consent

Exclusion criteria

- Ventricular tachyarrhythmia of transient or reversible causes
- Incessant ventricular tachyarrhythmia;
- Unstable angina, or acute MI, CABG, or PTCA within the past 4 weeks
- Correctable valvular disease that is the primary cause of heart failure
- Recent CVA or TIA (< 3 months)
- Persistent or permanent atrial arrhythmias
- Post heart transplant
- Renal failure (GFR<15 ml/min/1.73m2) or on dialysis
- Previous implant with a CRT/CRT-D device
- Concurrent implant with another pacemaker or ICD
- Already included in another clinical study that could confound the results of this study
- Life expectancy less than 1 year;
- Inability to understand the purpose of the study or to understand and complete the QOL questionnaire
- Unavailability for scheduled follow-up or refusal to cooperate
- Sensitivity to 1 mg DSP
- Age of less than 18 years
- Pregnancy
- Drug addiction or abuse
- Under guardianship

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2012
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Optimization algorithm in CRT-D device and Sorin RTip lead
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-06-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-11-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-12-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-04-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-07-2016

Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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
ClinicalTrials.gov	NCT01534234
CCMO	NL39676.075.12