Clinical Evaluation of the SonR atrial lead in the Paradym RF device

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Demonstrate a SonR atrial lead complication free rate superior to 90% after 3 months.Demonstrate the right ventricular auto threshold performance by comparing manual and automatic measurements performed at 1 month follow-up visit.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON34489

Source
ToetsingOnline

Brief title
Klinische evaluatie van de SonR atriale electrode in de Paradym RF ICD

Condition

- Cardiac arrhythmias

Synonym
heart failure, ventricular dysssynchrony

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CRT-D, Paradym RF, SonR lead

Outcome measures

Primary outcome

Atrial lead complication rate superior to 90% after 3 months.

Comparison of automatic and manual right ventricular stimulation threshold

after 1 month.

Secondary outcome

Report Serious Adverse Events and Adverse Events.

Report electrical functionality of the ICD.

Report electrical functionality of the SonR atrial lead.

Report hemodynamic performance measurements from the SonR atrial lead.

Study description

Background summary

Optimisation of AV and VV delays improves the hemdynamic functionality, and positively influences left ventricular remodeling. This study assesses the contribution of the use of the SonR atrial lead together with the Paradym RF device.

Study objective

Demonstrate a SonR atrial lead complication free rate superior to 90% after 3 months.
Demonstrate the right ventricular auto threshold performance by comparing manual and automatic measurements performed at 1 month follow-up visit.

Study design

Prospective, multi-centre, non-randomized, pivotal trial.

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 biventricular defibrillator and chronic heart failure.

Exclusion criteria

Contra-indication for standard pacing.

Contra-indication for ICD therapy.
Acute myocarditis.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-11-2010
Application type:	First submission
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
CCMO	NL33151.075.10