Clinical Evaluation of the Physiological Diagnosis Function in the Paradym CRT device

Published: 14-07-2010
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Demonstrate the sensitivity of the diagnostic feature "Physiological Diagnostic" (PhD) to detect clinically relevant HF-related events and to demonstrate a reasonable number of false positive indications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON35038

Source
ToetsingOnline

Brief title
CLEPSYDRA

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
exercise tolerance, minute ventilation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biventricular ICD, diagnostic function, Paradym CRT, PhD

Outcome measures

Primary outcome

Sensitivity of the PhD-inication in detecting HF events (device indicated) in relation to all HF-related clinical events.

At least one of the following present: hospital admission, emergency room visit requiring intravenous drug treatment, invasive intervention, admission to intensive care, initiation of intravenous drug treatment without hospital admission, death.

Mean number of false positives per year per patient.

Success is defined as mean rate for study population statistically significantly less than two false positives per patient per year.

Secondary outcome

Sensitivity of Paradym PhD-indication in detecting HF events (device indicated HF event) in relation to all HF events related to oral treatment modification.

Reported co-morbidity that was related to a PhD-indication in the device memory.

Reported Adverse Events.

Study description

Background summary

Evaluation of an additional diagnostic function in a biventricular defibrillator.

Study objective

Demonstrate the sensitivity of the diagnostic feature "Physiological Diagnostic" (PhD) to detect clinically relevant HF-related events and to demonstrate a reasonable number of false positive indications.

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 biventricular defibrillator and chronic heart failure.

Exclusion criteria

Contraindication for standard pacing.
Contraindication for ICD therapy.
Abdominal implantation site.
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):	02-09-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	ICD

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-07-2010
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	NL31468.075.10