Safety and electrical performances of Navigo leads equipped with IS4 connector

Published: 09-11-2017
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Safety and electrical performances evaluation of Navigo left ventricular leads with an IS4 connector, which are used at the implant of a cardiac resynchronisation system.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON47542

Source
ToetsingOnline

Brief title
Navigator

Condition

- Heart failures

Synonym
heart failure, pump failure

Research involving
Human

Sponsors and support

Primary sponsor: Sorin CRM SAS, LivaNova Group
Source(s) of monetary or material Support: sponsor: Sorin CRM SAS

Intervention

Keyword: cardiac resynchronisation, CRT, IS4 connector, LV lead

Outcome measures

Primary outcome

Resistance, stimulation threshold, sensing values of the Navigo lead at

pre-discharge, 2, 6, 12, 18 and 24 months.

Safety of the lead at 6, 12, 18 and 24 months.

Document Serious Adverse Events.

Document handling performance.

Document percentage of successful implants.

Document number of patients with multi-point pacing.

Document number of patients with a stimulation threshold of the Navigo lead of

less than 2.5 Volts x 0.5 milliseconds for at least 2 different vectors;

without phrenic nerve stimulation.

Secondary outcome

Not applicable.

Study description

Background summary

Safety and electrical performances evaluation of Navigo left ventricular leads with an IS4 connector, which are used at the implant of a cardiac resynchronisation system.

Study objective

Safety and electrical performances evaluation of Navigo left ventricular leads with an IS4 connector, which are used at the implant of a cardiac resynchronisation system.

Study design

Pre-market, prospective, single-arm, international, multicentre, observational study with e limited number of additional electrical measurements of the defibrillator at the 2 to 3-month follow-up visit.

Study burden and risks

Very limited additional burden for the patient at the 2-month follow-up visit; this visit will take app. 15 minutes longer.

Limited risk: a new type of left ventricular lead is being used, from a manufacturer with more than 20 years experience - and excellent results (ever since the introduction of this therapy).

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 CRT implant, upgrade from ICD to CRT
signed and dated informed consent

Exclusion criteria

intolerace of dosage dexamethasone higher than 300 picograms
transvenous LV cardia vein access impossible

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2018

Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-11-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-02-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	01-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-08-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-08-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL61815.075.17