Safety and Electrical Performance Evaluation of Invicta Leads Models Equipped with DF4 Connector.

Published: 22-11-2018
Last updated: 10-01-2025

Safety and electrical performance evaluation of Invicta leads moodels equipped with DF-4-connector.Clinical study to support the submission for acquiring the CE-mark.

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

Summary

ID

NL-OMON46106

Source
ToetsingOnline

Brief title
FRIENDS

Condition

- Cardiac arrhythmias

Synonym
cardiac arrhythmia, heart rhythm disorders

Research involving
Human

Sponsors and support

Primary sponsor: MicroPort CRM B.V.
Source(s) of monetary or material Support: Industry sponsor;being Sorin CRM SAS.

Intervention

Keyword: DF-4 shock electrode., ICD-lead, Invicta

Outcome measures

Primary outcome

Lead safety after 3 months: absence of any lead-related complications.

Electrical performance after 3 months: stable stimulation thresholds in the

right ventricle (expected values: 1 Volt +/- 0,5 Volt and a pulse duration of

0,5 ms.

Secondary outcome

Document electrical performance of the right ventricular lead: sensing

thershold in mV, impedance in Ohm, stimulation threshold in Volt x ms.

Document good detection of VT and VF, as well as adequate delivery of therapy

(anti-tachy pacing or defibrillation shock).

Safety of the right ventricular lead.

Handling assessment of the right ventricular lead.

Successful implant percentage of the right ventricular lead.

Study description

Background summary

Safety and electrical performance evaluation of Invicta leads moodels equipped with DF-4-connector.
Clinical study to support the submission for acquiring the CE-mark.

Study objective

Safety and electrical performance evaluation of Invicta leads moodels equipped with DF-4-connector.

Clinical study to support the submission for acquiring the CE-mark.

Study design

Pre-market, prospective, longitudinal single-arm, international (European), multi-centre.

Study burden and risks

No additional burden for the patient.
No expected additional benefit for the patient, other than an easier implant procedure and electrical connection trustworthiness.

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 ICD or CRT/D implant (defibrillator) according to ESC guidelines.

Exclusion criteria

Tricuspid valvular disease or mechanical heart valve.
Active myocarditis.
Pregnant, or not taking/using contraceptives when of a fertile age.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-11-2018
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-11-2018
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
Other	CIV-PT-025366
CCMO	NL67315.075.18

Study results

Results posted: 11-04-2019

First publication
11-04-2019