Safety and Performance of Invicta ventricular DF4 leads with active fixation.

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

Summary

ID

NL-OMON54422

Source
ToetsingOnline

Brief title
APOLLO

Condition

- Cardiac arrhythmias

Synonym
heart rhythm disorders; cardiac arrhythmias

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 (part of Microport CRM).

Intervention

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

Outcome measures

Primary outcome

Early safety and performance endpoint:

• Freedom from Unanticipated Serious Adverse Device Effect (USADE) from RV lead, from attempt to implant to 1M. The endpoint will consider any serious adverse device effect which by its nature, incidence, severity or outcome was not identified in the risk analysis report.
The anticipated patients* free-rate is 100%, against a priori performance goal of 95%.

• Summarize RV pacing threshold amplitude (V), RV pacing impedance (Ohm), endocardial R wave amplitude (mV), defibrillation coil impedance (Ohm) at 1 month.

The result of this analysis will not determine the success or failure of the study.
This endpoint has been selected in order to grow a body of evidence (that starts with few pts at 1M, and ends with a large population at 2 years): the assessment of this analysis will be done by the Data Safety Monitoring Board (DSMB).

The study will have 2 co-primary endpoints, assessed independently on the subjects enrolled in Phase I:

• INVICTA lead safety at 3 months: freedom from RV lead-related complications that occurred up to 90 days from first attempt to implant the INVICTA lead. A complication is defined as any serious adverse event related to the INVICTA lead (SADE) that resulted in patient death or required an additional invasive intervention. Lead-related complications may occur during or after the implant procedure. The anticipated complication-free rate is 0.97, against a priori performance goal of 0.90.

• INVICTA lead performance at 3 months: RV pacing threshold at 3 months from successful implant. The anticipated pacing threshold value is 1.0±0.5 V at 0.5 ms, against a priori performance goal of <1.25 V.

Secondary outcome

1. INVICTA pacing threshold amplitude (V), RV pacing impedance (Ohm), endocardial R wave amplitude (mV), defibrillation coil impedance(Ohm) at Implant, pre-hospital discharge, 1 month, 3, 6, 12, 18 and 24 months after implant.

2. Efficacy of INVICTA leads to terminate ventricular tachycardia (VT) and/or ventricular fibrillation (VF) by endocardial shock therapies, when a defibrillation test is performed (at physician discretion) or a spontaneous ventricular arrhythmia occurs.

3. Acute INVICTA lead complications (<=30 days post-implant).

4. Chronic INVICTA lead complications (>30 days post-implant).

5. Daily INVICTA autothreshold values (V) from implant to M1 visit (applicable if implanted with an ICD model with auto-threshold feature enabled).

6. INVICTA lead handling assessment.

7. INVICTA lead implant success rate.

8. SAE's up to 24 months post implantation

Tertiary endpoints:

1. Acute complication rates as a function of the lead position (apical vs septal, <= 30 days post-implantation).

2. Chronic complication rates as a function of the lead position (apical vs septal, > 30 days post-implantation).

Electrical performances as a function of the lead position (apical vs septal), up to 24 months post-implantation

Study description

Background summary

Safety and performance of Invicta ventricular DF4 leads with active fixation.

Study objective

Safety and performance of Invicta ventricular DF4 leads with active fixation.

Study design

Pre-market, prospective, logitudinal, single arm international (European) study.

Study burden and risks

There is no addtional burden for the patient.
Nor is there an expected benefit for the patient, other than an easier implant procedure and an improved reliability od the electrical connections.

Contacts

Public
Microport CRM B.V.

Paasheuvelweg 25
Amsterdam 1105 BP
NL
Scientific
Microport CRM B.V.

Paasheuvelweg 25
Amsterdam 1105 BP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Indication for an ICD or CRT-D implant, according to ESC guidelines.
2. Scheduled for a de novo implant of an ICD (VR, DR) or CRT-D, manufactured by Microport CRM, equipped with a DF4-connector.
3. Dated and signed Informed Consent.

Exclusion criteria

1. Tricuspid valvular disease, or tricuspid valve replacement of any kind.
2. Transient tachy-arhythmias due to reversible causes.
3. Contra-indication to a maximum single dose of 330 ug dexamethasone sodium phosphate (DSP).
4. Active myocarditis.
5.Previous implant of a pacemaker, ICD or CRT-D device and leads.
6. Enrolled in another study that may confound the results of the Apollo study.
7. Inability to understand the purpose of the study.
8. Under the age of 18.
9. Pre-menopausal women.
10. Drug addiction or drug abuse.
11. Life expectancy less than 1 year.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-06-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-10-2023
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
Other	EUDRA-CT 2020-AOO963-36
CCMO	NL73839.075.20