Assessment of the Axone micro quadripolar lead for enhanced cardiac resynchronization therapy.

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Assessment of the Axone micro quadripolar electrode for enhanced cardiac resynchronization therapy.A clinical study designed to obain the CE-mark.This new, quadripolar micro electrode allows for easier placement of the left ventricular lead,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON50818

Source
ToetsingOnline

Brief title
ASTRAL

Condition

- Heart failures

Synonym
decreased pump function of the heart, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Microport CRM B.V.
Source(s) of monetary or material Support: Sorin CRM SAS (part of Microport CRM)

Intervention

Keyword: cardiac resynchronization therapy, heart failure, quadripolar left ventricular lead

Outcome measures

Primary outcome

The study has 2 co-primary endpoints:

1. Co-primary safety endpoint, defined as a complication free ratio of the

Axone system 6 months post implant.

2. Co-primary performance endpoint, defined as successful left ventricular

stimulation 6 months post implant.

Secondary outcome

Secondary endpoint of the study is successful bi-zonal stimulation of the left

ventricle 6 months post implant.

Study description

Background summary

Assessment of the Axone micro quadripolar electrode for enhanced cardiac resynchronization therapy.
A clinical study designed to obain the CE-mark.
This new, quadripolar micro electrode allows for easier placement of the left ventricular lead, providing the physician with more options for successful cardiac resynchronization therapy.

Study objective

Assessment of the Axone micro quadripolar electrode for enhanced cardiac resynchronization therapy.
A clinical study designed to obain the CE-mark.
This new, quadripolar micro electrode allows for easier placement of the left ventricular lead, providing the physician with more options for successful cardiac resynchronization therapy.

Study design

Pre-market, interventional, prospective, longitudinal, single-arm, open label, multicenter-study (European).

Intervention

Implant of the Axone quadripoloar left ventricular electrode.

Study burden and risks

There is a minor additional burden for the patient, in the sense that 1 additional follow-up visit is needed 1 month after implant.
Limited additional risk for the patient: a new left ventricular lead will be implanted (manufactured by a company with more than 50 years experience in the development of devices for cardiac stimulation).

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

1. indication for a CRT device implant
2. de novo implant of a Platinium 4LV CRT-D device (or any newer model), manufactured by Microport CRM
3. reviewed, signed and dated informed consent

Exclusion criteria

1. LV lead previous implant attempt
2. upgrade to a CRT-D from a previously implanted pacemaker or ICD, or CRT-D replacement
3. known allergy to contrast media
4. tricuspid valve disease or replacement of tricuspid valve
5. severe renal failure
6. active myocarditis
7. stroke, myocardial infarction or cardiac revascularization within 40 days prior to implant
8. previous heart transplant or on heart transplant list
9. life expectancy less than 1 year
10. included in another study which may confound the results in this study
11. pre-menopausal women, including pregnant and breastfeeding women
12. less than 18 years old or under guardianship
13. incapacitated, inability to understand the purpose of the study or to adhere to the follow up protocol
14. diagnosis of drug addiction

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-01-2022
Enrollment:	27
Type:	Actual

Medical products/devices used

Generic name:	Implant of a new quadripolar left ventricular lead
Registration:	No

Ethics review

Approved WMO Date:	14-01-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-07-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-12-2023
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
ClinicalTrials.gov	NCT04463641
CCMO	NL76054.075.20