Clinical Investigation of the ENO/TEO/OTO Pacing System under MRI environment

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Primary endpoint of the study is the confirmation of the safety and effectiveness of the ENO/TEO/OTO pacing system in an 1.5 Tesla and 3.0 Tesla environment, without scanning exclusion zone.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50027

Source
ToetsingOnline

Brief title
CAPRI

Condition

- Other condition

Synonym
Pacemaker safety and efficacy in an MRI environment

Health condition

Pacemaker system safety and efficacy in an MRI environment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MRI, pacemaker

Outcome measures

Primary outcome

The study has 1 primary endpoint: absence of MRI related complications within 1 month post MRI exam.

An MRI related complication is defined as a Serious Adverse Event leading to death, or an invasive intervention, or a Device Deficiency which has led to loss of pacemaker functionality, as adjucated by an independent Clinical Events Committee.

The primary endpoint will be assessed seperately for both arms (1.5 Tesla, 3.0 Tesla).

Secondary outcome

The 4 secondary endpoints are:

- stability of the ventricular pacing threshold (threshold increase < 0,5 Volt at 0.5 milliseconds)
- stability of the atrial pacing threshold (threshold increase < 0,5 Volt at 0.5 milliseconds)
- stability of the ventricular sensing threshold (sensing amplitude decrease < 50% of the initial value, unless this value was 4mV or less: in which case the

patient will not be part of the analysis)

- stability of the atrial sensing threshold (sensing amplitude decrease < 50%

of the initial value, unless this value was 1mV or less: in this case the

patient will not be part of the analysis

Also the secondary endpoints will be analysed for each arm (1,5 Tesla; 3.0

Tesla) seperately.

Study description

Background summary

Collection of data concerning the safety and effectiveness of the ENO/TEO/OTO pacing system in an MRI environment.

Study objective

Primary endpoint of the study is the confirmation of the safety and effectiveness of the ENO/TEO/OTO pacing system in an 1.5 Tesla and 3.0 Tesla environment, without scanning exclusion zone.

Study design

Interventional, prospective, muliti-centre, open label, two-arm, parallel, non-comparative, non-randomised study.

Intervention

An MRI exam at minimum 6 weeks post pacing system implant, within 8 weeks of enrolment of the patient in the study.

Study burden and risks

There is no additional risk for the patient; additional burden consists of a 40-minute MRI exam, maximum duration 40 minutes (60 minutes when preparation and conclusion is taken into account).

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

Implanted with an ENO/TEO/OTO single or dual chamber pacemaker system with Vega lead(s).
Agree to undergo a non-clinically indicated MRI scan, without intravenous injection or sedation.
Informed consent.
Available for follow-up.

Exclusion criteria

Included in another study, that may confound results in this study.
Presence of other cardiac implants.

Presence of other - non-MRI compatible - implants.
History of brain aneurysm with ferromagnetic clipping.
Presence of cochlear implants.
Tattoos in area where MRI coil is placed.
Planned cardiac surgery within 3 months of inclusion.
Planned MRI scan within 3 months of inclusion.
Aged under 18, in detention, or under guardianship.
Known pregnancy, breast-feeding or of child-bearing age without adequate contraceptive method.
Unavailable for follow-up.
Conflict of interest with sponsor, investigator or institution.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2020
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	09-06-2020
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
ClinicalTrials.gov	NCT03811691
CCMO	NL71015.075.19