ImageReadyTM pacing system data collection in patients undergoing Magnetic Resonance Imaging.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26814

Source
Nationaal Trial Register

Brief title
INFINITE MRI

Health condition

Magnetic resonance Imaging
MR conditional pacemakers
bradyarrhyhtmias

Sponsors and support

Primary sponsor: Giovanni Raciti
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Source(s) of monetary or material Support: Guidant Europe SA / NV,
a Boston Scientific Company
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Intervention

Outcome measures

Primary outcome

No impact of MRI on device function, lead parameters and patient conditions for the CE-marked ImageReady™ MR Conditional Pacing System when used under the labeled Conditions of Use.

The study will collect standard device measurement through device interrogation pre- and post- MRI scan. Device measurements will include lead measurements (amplitude, threshold and impedance).

Data from this study will be used to support the evidence of clinical performance of the ImageReady™ MR Conditional Pacing System following a MRI scan when used under the labeled Conditions of Use, and may be used to support regulatory submissions for the approval of the system worldwide.

Secondary outcome

N/A

Study description

Background summary

INGENIO MRI/ FINELINE II ImageReadyTM pacing system data collection in patients undergoing Magnetic Resonance Imaging (INFINITE MRI).

Background of the research:

Magnetic resonance imaging (MRI) is now the imaging modality of choice for many neurological and musculoskeletal conditions. In the past, implanted cardiac devices including pacemakers (PM) have been contraindicated by MRI scanner, due to the potential for adverse effects. Boston Scientific INGENIO pacemakers and FINELINE II Sterox endocardial pacing leads (ImageReady™) have been labeled as a “MR Conditional Pacing System” when used in

the MRI environment under the labeled Conditions of Use. Interest in collecting human data to confirm performance of this pacing system when used in MRI environments is high, with the collection of data from patients undergoing an MRI scan of key importance.

Objective of the research:

Objective of the INFINITE MRI Study is to collect data on the ImageReady™ MR Conditional Pacing System in subjects already implanted with the system according to standard medical guidelines for PM implantation undergoing a MRI scan under the labeled Conditions of Use. The study is aimed at providing confirmatory data of no impact of MRI on device function, lead parameters and patient conditions for the CE-marked ImageReady™ MR Conditional Pacing System when used under the labeled Conditions of Use.

The study will collect standard device measurement through device interrogation done before MRI scan, post an MRI scan and at a 30 day follow up. Device measurement will include the following lead: amplitude, threshold and impedance.

Study Design:

The INFINITE MRI Study is a prospective, non-randomized non-blinded, multicenter, single arm study. Study will enroll up to 20 subjects at approximately two centers in Europe.

Study population:

Main inclusion criteria:

1. Age 18 or above, or above legal age and willing and capable of giving informed consent specific to national law;

2. Patients already implanted with ImageReady™ MR Conditional Pacing System, according to standard medical guidelines for pacemaker implantation;

3. Willing and capable of participation to the procedures indicated in the protocol.

Main exclusion criteria:

1. Patients implanted with other cardiac-related implanted devices or accessories other than the ImageReadyTM MR Conditional Pacing System;

2. Low life expectancy (< 1 year);

3. Severe comorbidities that, according to clinical judgment, pose patient at risk to undergo MRI.

Study objective

The study is aimed at providing confirmatory data of no impact of magnetic resonance on pacemaker device function, lead parameters and patient conditions for the CE-marked ImageReady™ MR Conditional Pacing System (INGENIO MRI pacemaker + FINELINE II leads)when used under the labeled Conditions of Use.

Study design

1. Enrollment;

2. MRI visit;

3. One month follow up: 30 days +/-7 days after MRI visit.

Intervention

There are no invasive interventions planned: INFINITE MRI Study collects data on the ImageReady™ MR Conditional Pacing System in subjects already implanted with the system according to standard medical guidelines for PM implantation and meets the labeled MRI Conditions of Use. Patients will undergo a MRI scan not for diagnostic purposes under the labeled Conditions of Use.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 or above, or above legal age and willing and capable of giving informed consent specific to national law;

2. Patients already implanted with ImageReady™ MR Conditional Pacing System, single or dual chamber, including INGENIO MRI or ADVANTIO MRI pulse generators with FINELINE II Sterox or FINELINE II Sterox EZ endocardial lead(s), according to standard medical guidelines for pacemaker implantation;

3. Willing and capable of participation to the procedures indicated in the protocol.

Exclusion criteria

1. Patients implanted with pulse generator location outside of left or right pectoral regions;

2. Patients implanted with other cardiac-related implanted devices or accessories other than the ImageReadyTM MR Conditional Pacing System;

3. Abandoned leads or pulse generators (PG);

4. Evidence of a fractured lead or compromised PG-lead system integrity;

5. Low life expectancy (< 1 year);

6. Severe comorbidities that, according to investigator clinical judgment, pose patient risk to undergo MRI;

7. Pregnant women or women of childbearing potential.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-02-2013
Application type:	First submission

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
NTR-new	NL3711
NTR-old	NTR3874
Other	Boston Scientific : C1897
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A