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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38918

Source
ToetsingOnline

Brief title
INFINITE MRI

Condition

- Other condition
- Cardiac arrhythmias

Synonym
Cardiac Rhythm disease ; Bradyarrhyhtmia

Health condition

Magnetic Resonance Imaging (MRI)

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Cooperation International
Source(s) of monetary or material Support: Ministerie van OC&W,Guidant Europe

Intervention

Keyword: Bradyarrhyhtmia, Cardiac Rhythm Disease, Magnetic Resonance Imaging (MRI), pacemaker

Outcome measures

Primary outcome

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.

The study has no primary endpoint and is not hypothesis driven.

Secondary outcome

Not applicable

Study description

Background summary

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 labeling, due to the potential for adverse effects including elevated pacing thresholds; failure of capture due to tissue heating at the tip of the endocardial pacing lead and induced arrhythmias due to unintended cardiac stimulation. New generations of PMs have been designed to allow patients to have a MRI scan under certain conditions of use and have been labeled as MR Conditional. Boston Scientific*s (BSC) new generation of PMs, the Ingenio MRI family, includes purposeful design enhancements to allow exposure in the MR environment under specific conditions of use. The use of the Ingenio MRI family of PMs together with FINELINETM II Sterox family of endocardial pacing leads

has been labeled as a *MR Conditional Pacing System* when used in the MRI environment under the labeled Conditions of Use. Ingenio MRI PM family received CE Mark in July 2012 and 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. However, despite the fact that it has been reported up to 17% of PM patients are indicated for MRI within an year of pacemaker implant, the availability of supportive clinical data is limited. For this reason, and in light of the interest from regulatory and healthcare bodies world-wide, data prospectively obtained from PM patients who undergo a MRI scan has been requested to support the use of MR Conditional systems. Such data can be collected in medical facilities that have already implanted the MR Conditional pacing system simply by confirming proper device function following a dedicated MRI scan sequence not designed for the purposes of diagnosis.

Study objective

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 and meets the labeled MRI Conditions of Use, 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 pre- and post- MRI scan. MRI scan in this study is a non-clinically indicated procedure and is not planned for diagnostic purposes. 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.

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, who agree to participate in the study by signing informed consent, will undergo a MRI scan and perform a device follow up at one month.

Study burden and risks

Risks: subjects that will be enrolled in the INFINITE MRI Study are patients already implanted with with ImageReady* MR Conditional Pacing System according to standard medical guidelines for PM implantation. All measurements indicated in this protocol are done according to approved labeling for the ImageReady* MR Conditional Pacing System. MRI in patients implanted with the ImageReady* MR Conditional Pacing System is considered safe when complying with Conditions of Use as indicated both in the labeling and in this study protocol. Known adverse events associated with the ImageReady* MR Conditional Pacing System when undergoing MRI under the labeled Conditions of Use are extremely rare and none is anticipated to occur in the limited sample of this study. Other risks associated to MRI and not specifically related to the ImageReady* system are extremely rare provided that appropriate precautions are followed according to radiology standards. Risks are additionally mitigated by appropriate patient selection according to the criteria of the present protocol and by using non-invasive procedure (no vein puncture, no contrast enhancing agents), unless needed for specific MR diagnostic purposes, that are not part of the present study.

Benefits: with respect to MRI scanning, no diagnostic data will be generated by the MRI scan in the INFINITE MRI study, unless (a) an MRI indication for the patient already exists or (b) according to site indications and/or patient decision. Therefore, there should be no direct benefit for the patient in participating to this study. Data from this study will however, generate confirmatory evidence of no impact of MRI on standard device function of the CE-marked ImageReady* MR Conditional Pacing Systems confirming the clinical safety and performance of the system and potentially providing evidence to support regulatory approval of the system in other geographies worldwide.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age 18 or above, or above legal age and willing and capable of giving informed consent specific to national law
• Patients already implanted with ImageReady* MR Conditional Pacing System, including INGENIO* MRI or ADVANTIO* MRI pulse generators with FINELINE* II Sterox endocardial lead(s), according to standard medical guidelines for pacemaker implantation.
• Willing and capable of participation to the procedures indicated in the protocol.

Exclusion criteria

• Patients implanted with pulse generator location outside of left or right pectoral regions
• Patients implanted with other cardiac-related implanted devices or accessories other than the ImageReadyTM MR Conditional Pacing System
• abandoned leads or pulse generators (PG)
• evidence of a fractured lead or compromised PG-lead system integrity
• Low life expectancy (< 1 year)
• Severe comorbidities that, according to clinical judgment, pose patient at risk to undergo MRI
• Women of childbearing potential who are or might be pregnant at the time of study enrollment or ImageReady MR Conditional Pacing System implant (method of assessment upon physician*s discretion)

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-05-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL43816.100.13
Other	NTR3874 + ongoing www.clinicaltrials.gov