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

Gepubliceerd: 25-02-2013 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26814

Bron
Nationaal Trial Register

Verkorte titel
INFINITE MRI

Aandoening

Magnetic resonance Imaging
MR conditional pacemakers
bradyarrhyhtmias

Ondersteuning

Primaire sponsor: Giovanni Raciti
Clinical Trial Manager
Phone: +39 02 26983213
E-mail: Giovanni.Raciti@bsci.com
Overige ondersteuning: Guidant Europe SA / NV,
a Boston Scientific Company
Clinical CRM Department
Green Square

Lambroekstraat 5D
1831 Diegem,
Belgium

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Enrollment;

2. MRI visit;

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

St. Antonius Ziekenhuis
Koekoekslaan 1
Lucas V.A. Boersma
Nieuwegein 3435 CM
The Netherlands

Wetenschappelijk

St. Antonius Ziekenhuis
Koekoekslaan 1
Lucas V.A. Boersma
Nieuwegein 3435 CM
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-04-2013
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3711
NTR-old	NTR3874
Ander register	Boston Scientific : C1897
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A