INGENIO 2 /INGEVITY MRI device family data collection in patients undergoing Magnetic Resonance Imaging

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28451

Bron
NTR

Verkorte titel
INFINITE 2 MRI

Aandoening

Pacemakers, Magnetic Resonance Imaging, hartritmestoornis,bradyaritmie

Ondersteuning

Primaire sponsor: study sponsored by:
Guidant Europe SA / NV,
a Boston Scientific Company
Clinical CRM Department
Green Square
Lambroekstraat 5D
1831 Diegem,
Belgium
Overige ondersteuning: Guidant Europe SA / NV,
a Boston Scientific Company

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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 2 pacemakers and INGEVITY MRI 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.

Onderzoeksopzet

- enrollment (after implant of pacemaker)
- MRI visit (at least 6 weeks after pacemaker implant, according to Conditions of use)
- standard of care follow up visit, one month after MRI visit.

Onderzoeksproduct en/of interventie

Subjects are enrolled when already implanted according to standard medical guidelines for pacemaker implantation and will undergo a Magnetic Resonance Imaging (MRI) scan under the labeled Conditions of Use.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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, according to standard medical guidelines for pacemaker implantation.
• Willing and capable of participation to the procedures indicated in the protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Patients implanted with other cardiac-related implanted devices or accessories other than the ImageReadyTM MR Conditional Pacing System
• Low life expectancy (< 1 year)
• Severe comorbidities that, according to clinical judgment, pose patient at risk to undergo

MRI

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4787
NTR-old	NTR4927
Ander register	: C1731

Resultaten