CapsureFix Novus Model 5076 Lead MRI study

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The purpose of this clinical study is to confirm safety and effectiveness of the Medtronic 5076 lead when used with Medtronic*s AdvisaDR MRI pacemker in the clinical MRI environment.

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

Summary

ID

NL-OMON38853

Source
ToetsingOnline

Brief title
5076 MRI study

Condition

- Cardiac arrhythmias

Synonym
arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Chest scan, MRI, Pacemaker Lead

Outcome measures

Primary outcome

Primary Objectives

* To assess the MRI-related complication-free rate one month post MRI.

* To demonstrate the non-inferiority of the MRI group compared to the Control group with regard to the proportion of subjects who experience an increase less than or equal to 0.50V in 1) atrial and 2) ventricular voltage thresholds at 0.5ms from the pre-MRI/waiting period to one month post-MRI/waiting period.

Secondary outcome

Secondary Objectives

* To demonstrate the non-inferiority of the MRI group compared to the Control group with regard to the proportion of subjects who experience a decrease less than or equal to 50% in 1) atrial and 2) ventricular sensing amplitude from the pre-MRI/waiting period to one month post-MRI/waiting period.

* To characterize occurrence of sustained ventricular arrhythmias and asystole seen during MRI scans.

Study description

Background summary

MRI has grown into one of the most widely used non-invasive imaging modalities. Various medical disciplines rely on the diagnostic capabilities of MRI because of its unique ability to discriminate soft tissues.
As a result, there is a growing need for medical devices, which are MRI safe. Medtronic already relaesed a number of MRI conditional pacemaker systems. The 5076 lead is a commonly used market-relaesed lead without MRI conditional labelling.

Study objective

The purpose of this clinical study is to confirm safety and effectiveness of the Medtronic 5076 lead when used with Medtronic*s Advisa DR MRI pacemker in the clinical MRI environment.

Study design

The 5076 MRI study is a prospective, randomized (2:1), controlled, non-blinded multi-site international study. The study design is based on the Advisa MRI SureScan pacing system clinical study, sponsored by Medtronic.
Subjects will have required follow up visits at baseline, implant, at 2 months, 9-12 weeks, one-week post-MRI/waiting period, and one-month post-MRI/waiting period. The MRI scans, including scans of the thoracic region, will be obtained for all subjects randomized to the MRI group will occur at the 9-12 weeks visit. The subjects in de control group have a wainting period.

Intervention

Two out of three subjects will obtain a MRI scan 9-12 weeks after implantation.

Study burden and risks

Two out of three subjects will undergo an MRI scan. For subjects in de control group there is a waiting period. Therefor all patients will come more often to the hopital for monitoring.

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

Patients has an indication for dual chamber pacemaker
Patients is willing to undergo elective MRI scanning

Exclusion criteria

Patient hac contraindication for dual chamber pacemaker
Patient has contraindication for an elective MRI Scan

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	23-04-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-04-2013
Application type:	Amendment
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
ClinicalTrials.gov	NCT01755143
CCMO	NL42906.100.13