Evera MRI Clinical Study

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The purpose of this clinical study is to confirm safety and effectiveness of the Medtronic Evera MRI ICD in a clinical MRI environment.

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

Summary

ID

NL-OMON53163

Source
ToetsingOnline

Brief title
Evera MRI

Condition

- Cardiac arrhythmias

Synonym
arrhythmia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Evera MRI, ICD, MRI scan

Outcome measures

Primary outcome

Primary Objectives:

Safety: To demonstrate an acceptable MRI-related event-free rate.

Efficacy: To demonstrate that the proportion of patients whose ventricular pacing capture threshold increases significantly one month post-MRI/waiting period is similar between the MRI group and the control group.

Secondary outcome

Secondary Objectives:

- To demonstrate an acceptable system-related complication rate.

- To demonstrate the system integrity of the high-voltage ICD component after MRI exposure.

- To demonstrate that the proportion of patients whose atrial pacing capture threshold increases significantly one month post-MRI/waiting period is similar between the MRI group and the control group.

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 released a number of MRI conditional pacemaker systems. The EveraMRI ICD is the world'sfirst

MRI-conditional ICD with no positioning restrictions.

Study objective

The purpose of this clinical study is to confirm safety and effectiveness of the Medtronic Evera MRI ICD in a clinical MRI environment.

Study design

The Evera MRI study is a prospective, randomized (2:1), controlled, non-blinded multi-site international study. The study
design is based on the 5076 MRI and the Advisa MRI SureScan pacing system clinical study.
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 the 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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Eligibility criteria

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

Inclusion criteria

Patient is indicated for the first time for an ICD implantation
Patient is willing and able to undergo elective MRI scanning

Exclusion criteria

Patient has contraindication for an ICD.
Patient has contraindication for an elective MRI scan.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2014
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	18-07-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT02117414
CCMO	NL48295.098.14