

# CapsureFix Novus Model 5076 Lead MRI study

Published: 25-03-2013

Last updated: 24-04-2024

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cardiac arrhythmias
<b>Study type</b>	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 released a number of MRI conditional pacemaker systems. The 5076 lead is a commonly used market-released 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 Advia DR MRI pacemaker 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 Advia 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 the control group have a waiting 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 the control group there is a waiting period. Therefore all patients will come more often to the hospital for monitoring.

## Contacts

### Public

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### Scientific

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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