MRI STUDY
ACCENT MRI* PACEMAKER AND TENDRIL MRI* LEAD IDE STUDY

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

Summary

ID

NL-OMON37204

Source
ToetsingOnline

Brief title
MRI Study

Condition

- Other condition
- Cardiac arrhythmias

Synonym
MRI safety Accent MRI systeem

Health condition

MRI onderzoek bij patienten met een pacemaker

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St. Jude Medical

Intervention

Keyword: Accent MRI Pacemaker, Bradycardia, MRI (Magnetic Resonance Imaging), Tendril MRI Lead

Outcome measures

Primary outcome

Safety

Safety of the Tendril MRI* lead will be evaluated in terms of freedom from RA

and RV lead-related complications for the acute (implant to 2 month visit) and

chronic (2 month visit through the 12 month visit) timeframes.

The safety of the Accent MRI system will be evaluated in terms of freedom from

MRI scan related complications in the month following the MRI scan.

Efficacy

Efficacy of the Tendril MRI* lead will be evaluated in terms of the change in

atrial and ventricular capture and sensing thresholds before and after the MRI

scan.

Secondary outcome

Safety

Safety of the Accent MRITM system will be evaluated in terms of freedom from

system-related complications through the 12 month visit.

Efficacy

Efficacy of the Tendril MRI* lead will be evaluated in terms of the atrial and

ventricular capture thresholds at the MRI Visit.

Study description

Background summary

Magnetic resonance imaging (MRI) is a diagnostic method to view high quality two and three dimensional images of the body. MRI does not use radiation, has few side effects and is very useful to view soft tissue. In 2007, an estimated 27.5 million MRI procedures were performed in the U.S. in 7,195 hospital and non-hospital sites.

According to the 2005 World Survey of cardiac pacing and cardioverter defibrillators, 223,425 new pacemakers were implanted in the United States in 2005 which is the highest of any country in the world. When compared to the 2001 survey, the 2005 survey also showed an increase in the number of pacemakers and defibrillators implanted throughout the world. It is estimated that 50-75% of the patients with implantable cardiac devices will develop an indication for a MRI scan during the lifetime of their device.

Magnetic resonance imaging systems generate three electromagnetic fields that are used to produce an image. These include a static magnetic field, a time varying gradient magnetic field, and a RF field. All three of these fields interact with implanted devices and could create hazards for the device, the patient, or both. Examples of these hazards include unwanted cardiac stimulation, heating near lead electrodes, image artifacts, and forces being applied to implanted components. Due to these issues, currently marketed pacemaker systems may be contraindicated for use in an MRI environment.

In the initial MRI studies, there were anecdotal reports of device malfunction or patient death associated with an MRI scan. None of these deaths occurred during physician supervised procedures. Over the past 10 years, there have been several reports of patients with implanted devices who successfully underwent magnetic resonance imaging. Even though many patients with implanted devices have successfully undergone MRI, *failing to identify an adverse event is not equivalent to demonstrating safety - especially when only a limited number of patients are studied*. In order to make MRI scans safer for patients with implantable cardiac devices, these devices need to be specifically designed and developed to mitigate the hazardous interactions in a MRI environment.

Study objective

The intent of this study is to evaluate the safety and efficacy of the implanted Accent MRI system, which includes the investigational St. Jude Medical Tendril MRI* lead and Accent MRI* pacemaker, in the MRI environment.

An MRI Activator* will be used in conjunction with Accent MRI system. The MRI Activator is a handheld device that allows the user to enable and disable MRI Setting, as well as check the status of MRI Setting in the pacemaker.

Study design

This is a prospective, multi-center, 2:1 randomized clinical study designed to evaluate the safety and efficacy of the Accent MRI System in a patient population indicated for implant of a pacemaker. In addition, the MRI Activator performance will be evaluated qualitatively.

The study will be conducted at a minimum of 50 centers and a maximum of 75 centers worldwide. A maximum of 97 enrollments will be allowed per center. The minimum requirement for completing this study is 363 patients (121 in control group and 242 in MRI group) completing their 1 month post MRI visit. Up to 484 patients (161 in control group and 323 in MRI group) will be enrolled to account for possible attrition.

Study burden and risks

There are no extra risks for the pacemaker implantation. The selected patient will receive this pacemaker system also if they would not participate in this research

The extra risks for the patients in this research are only due to the MRI scan. The MRI scan brings extra risks and discomfort. The MRI scan will not be used for diagnostic purpose. The MRI images will not be used for study purpose. If there are unexpected observations after the MRI scan this will be discussed by the physician with the patient and is needed referred to another physician.

Potential MRI Scan Adverse Events:
- Claustrophobia (fear of enclosed spaces)
- Mild diaphoresis (sweating)
- Hearing impairment (difficulty hearing)
- Sensation of bodily warmth
- Body stiffness related to immobility

There will be emergency personnel and equipment on hand for your safety. A cardiologist will be available during the procedure to administer any necessary care and to determine if the scan should be stopped for any reason. Please tell the study doctor, nurse or technician if you experience any unusual sensations or discomfort during the scan.

Potential MRI System Adverse Events:
• Lead electrode heating and tissue (heart muscle) damage resulting in loss of sensing or capture or both
• Device heating resulting in tissue damage in the implant pocket or patient discomfort or both
• Induced currents on leads resulting in continuous capture, VT/VF, hemodynamic collapse, or all three
• Damage to the device or leads causing:
• the system to fail to detect or treat irregular heartbeats
• the system to treat the patient*s condition incorrectly
• Damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer
• Movement or vibration of the device or leads
• Lead dislodgment (lead comes loose from the heart)
• Competitive pacing and potential for VT/VF induction due to ambulatory asynchronous pacing in MRI mode

There may be other risks to you that are not known at this time.

The physician will judge any unexpected/unwilling effects of the MRI scan on the pacemaker system, if needed. This could be solved by different program settings or, in the extreme case, a new system will be implanted.

Risks for Women of Childbearing Age
If you are pregnant or plan to become pregnant in the next 20 months, you should discuss your participation with your study doctor. Patients who become pregnant while taking part in the study should contact the study doctor right away. There are extra risks for pregnant women during pacemaker implant and during an MRI scan.

Contacts

Public
St. Jude Medical

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Eligible patients will meet all of the following:
1. Have an approved indication per ACC/AHA/HRS guidelines for implantation of a pacemaker
2. Wil receive a pacemaker systeem
3. Be willing to undergo an elective MRI scan without sedation
4. Be able to provide informed consent for study participation
5. Be willing and able to comply with the prescribed follow-up tests and schedule of evaluations
6. Is not contraindicated for an MRI scan

Exclusion criteria

Patients will be excluded if they meet any of the following:
1. Have an existing pacemaker or ICD. A new pacemaker and lead is required for enrollment
2. Have an existing active/inactive implanted medical device
3. Have a non-MRI compatible device or material implanted
4. Have a lead extender or adaptor
5. Be unable to fit in MRI bore; will come into contact with the magnet façade inside the MRI bore.
6. Have a prosthetic tricuspid heart valve
7. Are currently participating in a clinical investigation that includes an active treatment arm
8. Are allergic to dexamethasone sodium phosphate (DSP)
9. Are pregnant or planning to become pregnant during the duration of the study
10. Have a life expectancy of less than 12 months due to any condition
11. Patients with exclusion criteria required by local law (e.g., age)
12. Are unable to comply with the follow up schedule

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	ACCENT MRI PACEMAKER and TENDRIL MRI LEAD
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-01-2013
Application type:	First submission
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	NCT01576016
CCMO	NL41972.100.12