Long term follow-up of the Tendril STS and Isoflex leads in conjunction with the Assurity MRI* and Endurity MRI* Pacemakers within the 3T MRI Environment

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The objective of the study is to confirm the long-term safety of the Tendril STS and Isoflex leads, implanted with the Assurity MRI* or Endurity MRI* pacemakers, in patients undergoing clinically indicated 3T MRI scans.

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

Summary

ID

NL-OMON49741

Source
ToetsingOnline

Brief title
Brady 3T MRI

Condition

- Other condition
- Cardiac arrhythmias

Synonym
cardiac rythme disorders

Health condition

veiligheidsonderzoek in het kader van PMCF van MRI compatibele pacemaker in combinatie

met 3T MRI

Research involving
Human

Sponsors and support

Primary sponsor: Abbott Medical Nederland
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: 3T MRI Compatibility, Isoflex lead, Pacemaker, Tendril lead

Outcome measures

Primary outcome

Primary Endpoint#1: Proportion of subjects with a capture threshold increase of

* 0.5V at the permanently programmed pulse width from pre- MRI scan to

one-month post MRI scan.

Secondary outcome

Primary Endpoint #2: Proportion of subjects with a sensing amplitude decrease

of * 50% from pre- MRI scan to one-month post MRI scan.

Study description

Background summary

The main cause for concern with MRI scans, more so with 3T than 1.5T scanners due to their stronger electromagnetic fields (EMF), is the interaction between the EMF used to generate the images and any devices (e.g. stents, pacemakers, leads etc.) residing in the patient. Magnetic resonance imaging systems generate the diagnostic image using three EMFs. These include a static magnetic field, a time varying gradient magnetic field, and an 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 or incorrect cardiac stimulation, heating near lead electrodes, image artifacts, and forces being applied to implanted components [7]. Due to these

issues, certain currently marketed implantable cardiac device systems, including ICDs, may be contraindicated for use in an MRI environment, especially in pacemaker dependent patients.
According to the 2009 World Survey of cardiac pacing and cardioverter defibrillators, 282, 621 new pacemakers were implanted in 17 EU countries.
It is estimated that over 50% of the patients with implantable cardiac devices will develop an indication for an MRI scan during the lifetime of their device.
Numerous reports have been published, of patients with implanted devices who successfully underwent magnetic resonance imaging with 1.5T and 3T scanners [9-11]. In most cases, the scans were performed under controlled conditions, with careful telemetry monitoring of the patient by qualified personnel, during the imaging. The low rate of complications during these early studies led to a position statement by the European Society of Cardiology (ESC) in 2008 which considered the risks of MRIs in selected patients with implanted devices "acceptable" and set forth a protocol with careful selection criteria and best practices for safely performing MRI studies in these patients.
The pacemakers and leads being investigated currently have approval for 3T MRI scans in the EU. This study will also satisfy a PMCF requirement to maintain CE mark for 3T MR Conditional labeling.
3T MRI examination differs from the standard treatment within the MCL.

Study objective

The objective of the study is to confirm the long-term safety of the Tendril STS and Isoflex leads, implanted with the Assurity MRI* or Endurity MRI* pacemakers, in patients undergoing clinically indicated 3T MRI scans.

Study design

This is a prospective, multicenter trial, single arm clinical investigation designed to confirm the safety of SJM Tendril STS and Isoflex Optim leads, together with the Assurity MRI or Endurity MRI pacemakers, in patients undergoing 3T MRI scans.

Study burden and risks

All of the study procedures are part of standard-of-care, and would be done even if the patient were not enrolled in the study. Only standard of care is a 1,5T MRI and in this study a 3T MRI is done, furthermore can the 1 month FU visit be considered as additional study visit.

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

Eligible subjects will meet all of the following:
* Are implanted with a St. Jude Medical Assurity MRI or Endurity MRI pacemaker and Tendril STS 2088 or Isoflex 1944/1948 lead
* Capture threshold is stable and < 2.5V @ 0.5ms at the time of enrolment
* Are clinically indicated to undergo a 3T MRI scan
* Are willing and able to provide informed consent for study participation (legal guardian is NOT acceptable).
* Are willing and able to comply with the prescribed follow-up tests and schedule of evaluations.

Exclusion criteria

Subjects will be excluded if they meet any of the following:
* Are <18 years old (pediatric)
* Are currently participating in a clinical investigation that includes an

active treatment arm that may confound the results of this study as determined by Abbott.
* Known pregnancy, intends to become pregnant, or the patient is nursing.
* Have a life expectancy of less than 12 months due to any condition
* Contraindications for having a MRI scan including the presence of metal implants (e.g. stents, dental braces, pumps, hip or knee implants), abandoned or capped leads, or other devices (e.g. DBS).
* Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator*s opinion, could limit the subject*s ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	22-07-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	12-10-2020
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL68881.099.19