Model 20105 Lead Study

Published: 01-04-2015
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The purpose of this study is to evaluate the implant procedure and feasibility of the Model 20105 lead.

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

Summary

ID

NL-OMON42225

Source
ToetsingOnline

Brief title
Model 20105 Lead Study

Condition

- Cardiac arrhythmias

Synonym
Sinus node dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: industrie

Intervention

Keyword: 20105 LV DDD, Lead, LV DDD Lead

Outcome measures

Primary outcome

To evaluate the implant procedure related and lead related complications of the Model 20105 single pass lead during the first month of follow up.

Secondary outcome

1.The following rates will be evaluated:

- Medtronic Model 20105 lead implant success

- Medtronic Model 20105 fixation attempts

2.The following implant related times for patients with successful Model 20105 lead implants will be evaluated:

- Total implant

- Fluoroscopy

- Cannulation

- Model 20105 single pass lead placement time

3. All AEs (excluding unavoidable AEs * refer to Table 4) will be evaluated

4. The following electrical data will be collected at implant and scheduled follow-ups and analyzed:

- A and V voltage threshold(s) at 0.5 ms pulse width

- P and R-wave amplitude

- A and V impedance (implant only)

- Phrenic nerve stimulation threshold (implant only)

5. The Model 20105 lead implant handling characteristics such as pushability, ease of positioning, traceability, location of lead fixation, and ease of helix

fixation assessed through physician feedback will be evaluated.

Feedback from the investigators regarding the successful placement of the lead

at a location giving adequate electrical performance will be evaluated.

Study description

Background summary

Single passive fixation leads have been available for right sided pacing since the 1990s and still are widely used today. The advantages of a single pass lead are twofold: first, one can achieve atrial synchronous pacing with just one lead, meaning less prosthetic material and a shorter implant time and, second, because there is no atrial lead to pass, it lessens the chances of atrial lead dislodgement and atrial lead perforation.
However, there are disadvantage, first, it can only sense the atrium not pace the atrium and, second, the ventricular electrode affixes most readily in the right ventricle (RV) apex, today considered a less-than-optimal pacing site and third, the lead passes through the tricuspid valve, worsening effects of tricuspid regurgitation and contraindicating in patients with mechanical heart valves.
To overcome these limitations Medtronic has designed and manufactured Model 20105 lead which allows doing trans-venous sensing and pacing the left atrium (LA) and the left ventricle (LV). Thus the lead works as a left-sided single pass DDD lead (LV-DDD). The lead has two proximal electrodes for LA pacing and sensing and two distal ventricular electrodes placed in the coronary veins of the LV, thought to be a more physiologic site for pacing than the RV apex and the lead does not pass through the tricuspid valve. Since model 20105 is a left sided pacing lead it can be used for Brady pacing as well as Cardiac Resynchronization Therapy (CRT) applications. In CRT this lead may benefit in better optimization of timing between left atrial emptying and left ventricular filling as well as ejection.
The safety and feasibility of active fixation in a coronary vein with side helix is already studied in a human clinical study. The 20105 lead used side helix technology with lead body design closest to the market released Medtronic Attain Ability Model 4196 lead and Medtronic Attain Performa® Quadripolar Lead. No human clinical studies have previously been conducted with Model 20105 single pass lead. The risks and side effects associated with the implant of the Model 20105 Lead are the same as the implantation of any other market-released left ventricular lead.

Study objective

The purpose of this study is to evaluate the implant procedure and feasibility of the Model 20105 lead.

Study design

Model 20105 study is a prospective, multi-center, research study involving approximately 5 centers in up to 4 countries. Enrolled subjects will be followed at baseline, implant, pre-discharge, 1 month, 3 month and 6 month follow up.

Intervention

At baseline- ECG
Implant - holter/ venogram
PH - Echocardiogram/ ECG
1 mnd - geen extra handeling
3 mnd - holter
6 mnd - Echocardiogram

Study burden and risks

The Model 20105 lead has a little helix to fix the lead to the wall of your vein. There may be damage to the vein wall caused by the helix.

There is a potential risk that the Model 20105 lead is not sensing correctly the atrium or that it requires a high energy to stimulate the atrial chamber of your heart. This may cause you to feel a change in heartbeats or to consume faster the battery of the device.

The risks and side effects associated with the implant of the Model 20105 Lead are the same as the implantation of any other market-released left ventricular lead.

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

Patient has a cardiac pacing indication for sinus node dysfunction (dual chamber pacemaker)

Exclusion criteria

Patient is indicated for biventricular pacemaker or ICD
Patient is pacing dependent
Patient has a previous Pacemaker System
Patient has known coronary venous vasculature that is inadequate for lead placement
Patient has unstable angina pectoris or has had an acute myocardial infarction (MI) within the last month
Patient has had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past three months
Patient is not in sinus rhythm at implant
Patient is unable to tolerate an urgent thoracotomy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	LV DDD Lead
Registration:	No

Ethics review

Approved WMO

Date:	01-04-2015
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
CCMO	NL51340.098.14