Model 20066 LV Lead Study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON37840

Source
ToetsingOnline

Brief title
Model 20066 LV study

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: 20066 LV, Lead, LV lead

Outcome measures

Primary outcome

To evaluate the implant procedure related and lead related complications of the

Model 20066 LV lead during the first month of follow up.

Secondary outcome

To evaluate the implant success rate of the Model 20066 lead.

Study description

Background summary

Several randomized, controlled clinical trials (including MIRACLE, MIRACLE-ICD, CONTAK-CD, MUSTIC, PATH-CHF, COMPANION, MADIT CRT, and CARE-HF) have demonstrated the benefit of cardiac resynchronization therapy (CRT) among patients with moderate to severe heart failure (HF) with a prolonged QRS duration and a depressed Left Ventricular (LV) function. This therapy is delivered by a cardiac resynchronization system that consists of three pacing leads and an implantable pulse generator or implantable cardioverter defibrillator device.
Various lead models are required to suit the various sizes and shapes of patients* cardiac venous anatomy and implanting physician preferences. Despite advancements in Left Ventricle (LV) lead technology, the majority of post-implant invasive interventions to the Cardiac Resynchronization (CR) system are required due to the LV lead. In some patients, the LV lead requires revision or replacement due to an increase in pacing thresholds, dislodgement, phrenic nerve stimulation or lack of patient response to CR therapy. During the Attain Ability Model 4196 clinical study there were a total of 170 patients implanted and nine (9) patients had a LV lead related complication. All nine lead related complications occurred within 36 days of implant and were due to lead dislodgements.
The Model 20066 lead is a derivative of the market released Attain® Ability* Model 4196 lead and has been designed to reduce the occurrence of LV lead dislodgments. The Model 20066 lead has a small side helix that will allow physicians to securely place the lead in an area that was previously unstable with a non-active fixation LV lead. This lead may allow the implanting physician greater flexibility to place the lead in their desired location which has the potential to improve CRT response.

Study objective

The purpose of this study is to evaluate the implant procedure and feasibility of the Model 20066 LV lead.
The proposed Model 20066 study will provide data to assess the safety and feasibility of the Model 20066 fixation concept. It is also expected that this lead will reduce LV lead related complications and more specifically reduce the occurrence of LV lead dislodgments.

Study design

It is expected that when 30 patients are followed until their one month visit, Medtronic has collected sufficient data to determine whether it is feasible to use the Model 20066 fixation technology for the future LV guidance platforms. Incidence of Model 20066 guidance related complications will be assessed against a benchmark interest rate seen with the 4196 guideline LV (9 out of 170 = 5.3%). If 5 Model 20066 guidance related complications within the first month of follow-up investigations, participation will be suspended and evaluated by the research team. The study team will consult with the researchers to determine whether the Model 20066 guide complications were related to the guideline, implantation procedure training, installation guide or other unforeseen factor. Based on this consultation with the researchers a decision will be made again to continue participation or to conclude the study.

Study burden and risks

The risks associated with this study are expected to be similar to other LV lead implants and the benefit of increased lead stability out weight the risk of the known LV related complications.

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 meets CRT inclusion criteria according to the guidelines

Exclusion criteria

• Patient has a previous complete atrial based biventricular CRT system
• Patient has a previous LV lead implanted or previous implant attempt within 30 days of implant or ongoing AEs from previous unsuccessful attempt
• Patient has known coronary venous vasculature that is inadequate for lead placement

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	LV lead
Registration:	No

Ethics review

Approved WMO

Date:	25-07-2012
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
CCMO	NL40503.060.12