Attain performa Quadripolar Lead Clinical Study

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The purpose of this clinical trial is to evaluate the post-implant safety and efficacy of the Medtronic Attain Performa Quadripolar Model 4298, Model 4398, and Model 4598 Left Ventricular (LV) leads (*Attain Performa leads*) and also assess and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON37117

Source
ToetsingOnline

Brief title
Attain performa

Condition

- Heart failures

Synonym
depressed LV function, Heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Attain Performa, CRT therapy, LV lead, Quadripolar

Outcome measures

Primary outcome

Primary Safety Objective

• Attain Performa Safety Objective: Lead complication-free rate at 6 months

The Attain Performa lead will be considered safe if the proportion of subjects free of Attain Performa lead-related complications at 6 months post-implant is greater than 87% (i.e., the two-sided 95% lower confidence bound must be greater than 87%).

Primary Efficacy Objectives

The effectiveness of the lead will be evaluated based on two primary efficacy endpoints. The lead will be considered effective if both primary efficacy objectives are met simultaneously. The primary efficacy endpoints include pacing threshold assessments for the final programmed LV pacing configuration and for one additional programmable (non-programmed) pacing configuration while at least one of these two configurations must be a non-standard pacing vector.

• Attain Performa lead Efficacy Objective #1

The Attain Performa lead will be considered effective if the proportion of subjects with final programmed pacing vector having pacing voltage threshold less than or equal to 2.5 V at 0.5ms pulse width at 6 months post-implant is greater than 80% (i.e., the two-sided 95% lower confidence bound must be

greater than 80%).

• Attain Performa lead Efficacy Objective #2

The Attain Performa lead will be considered effective if the proportion of subjects with a non-programmed pacing vector having a pacing voltage threshold less than or equal to 4.0 V at 0.5ms pulse width at 6 months post-implant is greater than 80% (i.e., the two-sided 95% lower confidence bound must be greater than 80%).

Secondary outcome

Secondary Objectives

• Evaluate occurrences of PNS in all LV configurations, which will require:

1) Testing for presence of PNS at 8.0 V at 0.5ms performed at pre-hospital discharge, 3 months, 6 months, and 12 months post-implant for all LV lead vectors

2) Testing for PNS thresholds at 6 months and 12 months post-implant for all LV lead vectors where PNS is present at 8.0 V at 0.5ms

3) Assessment of all adverse events (AEs) for PNS that occur throughout study duration

• Summarize implant success rates

• Evaluate the following implant-related times: total implant, standard fluoroscopy, coronary sinus cannulation and successful lead placement

• Evaluate the handling characteristics of the Attain Performa leads

• Characterize the electrical performance of multiple pacing configurations (LV pacing capture threshold (PCT), sensing, impedance, and PNS) of the Attain

Performa leads at pre-hospital discharge, 1 month, 3 months, 6, months, and

every 6 months thereafter until study closure

• Characterize all AEs

• Characterize system related complications

• Estimate individual failure rate through 6 months post-implant

Study description

Background summary

Various LV lead models have been designed to suit the various sizes and shapes of patients* cardiac venous anatomies and implanting physician preferences. Despite advancements in LV lead technology, occasionally invasive post-implant interventions related to the LV lead may be required due to problems with high pacing thresholds, lead dislodgement or phrenic nerve stimulation (PNS) which might be important causes of failure to deliver CRT. Recent development of dual and quadripolar electrode LV leads has improved LV lead management by providing more options for ensuring chronic pacing with an acceptable threshold value, avoiding PNS occurrence by changing pacing configuration and termination of CRT therapy as well as reducing the risk of invasive treatments.

Study objective

The purpose of this clinical trial is to evaluate the post-implant safety and efficacy of the Medtronic Attain Performa Quadripolar Model 4298, Model 4398, and Model 4598 Left Ventricular (LV) leads (*Attain Performa leads*) and also assess and characterize their interaction with a Viva Quad Cardiac Resynchronization Therapy device (see Study Components section for details) with defibrillation capabilities (CRT-D) in patients indicated for a CRT-D device.

Study design

The Attain Performa* Quadripolar Lead Clinical Study is a prospective, non-randomized, multi-center, single arm, Investigational Device Exemption (IDE) clinical trial.

The Model 4298, Model 4398, and Model 4598 LV leads will be studied in this clinical trial, although the three lead models will be evaluated independently and will have separate study reports and regulatory submissions. The study

objectives for the three lead models will be identical and will investigate the safety and efficacy of the investigational leads along with an assessment of the overall system safety.
Subjects successfully implanted with an Attain Performa lead, Viva Quad CRT-D device, and Medtronic RV lead with DF4 connector will be followed at implant, pre-hospital discharge (PHD), 1 month, 3 months, 6 months and every 6 months thereafter until FDA approval is obtained or until study closure, whichever comes first. For this study, all system-related, procedure-related, cardiovascular-related and Serious Adverse Event information will be collected.

Intervention

Implantation with an Attain Performa lead, Viva Quad CRT-D device, and Medtronic RV lead with DF4 connector.

Study burden and risks

Risks assiciated with the LV implantation are compareble with every other LV lead implantation.

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 an indication for a CRT-D device.

Exclusion criteria

Patient has contraindications for standard transvenous cardiac pacing.

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):	28-01-2013
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	LV lead and CRT-therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-11-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-04-2013
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
Other	bekend na FDA approval
CCMO	NL41967.060.12