Attain StabilityTM Quad Clinical Study

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The purpose of this clinical study is to evaluate the safety and efficacy of the Attain Stability Quad MRI SureScan LV lead (Model 4798) in patients indicated for a de novo LV lead implant. This will be assessed through primary safety and primary…

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

Summary

ID

NL-OMON45275

Source
ToetsingOnline

Brief title
Attain StabilityQuad

Condition

- Heart failures

Synonym
desynchronization, heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Attain Stability Quad, LV lead, Model 4798, Quadripolar

Outcome measures

Primary outcome

Primary Safety Objective: Lead complication-free rate at 6 months

Primary Efficacy Objectives: Lead pacing capture thresholds at 6 months

Secondary outcome

The secondary objectives are descriptive in nature and are intended to provide

additional information about the Attain Stability Quad Model 4798 LV lead.

Study description

Background summary

The Attain Stability Quad MRI SureScan 4798 steroid-eluting, quadripolar electrode, IS4 transvenous lead is indicated for chronic pacing in the left ventricle via the cardiac vein, when used with a compatible Medtronic Cardiac Resynchronization Therapy (CRT) system. Extended bipolar pacing is available using this lead in combination with a compatible market approved CRT-D system and RV defibrillation lead.

Study objective

The purpose of this clinical study is to evaluate the safety and efficacy of the Attain Stability Quad MRI SureScan LV lead (Model 4798) in patients indicated for a de novo LV lead implant. This will be assessed through primary safety and primary efficacy endpoints.

Study design

The Attain Stability Quad Clinical Study is a prospective, non-randomized, multi-site, global, Investigational Device Exemption (IDE) interventional clinical study.

Intervention

All subjects included in the study will be implanted with a Medtronic market released de novo CRT-P or CRT-D device and an Attain Stability Quad MRI

SureScan LV Lead (Model 4798).

Study burden and risks

The risks are comparable to any other market-released LV lead implant.

Contacts

Public
Medtronic BV

Endepolsdomein 5
Maastricht 6229 GW
NL
Scientific
Medtronic BV

Endepolsdomein 5
Maastricht 6229 GW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient meets CRT implant criteria as determined by local regulatory and/or hospital policy.
- Patient has signed and dated the study-specific Consent Form

Exclusion criteria

- Patient has had a previous unsuccessful LV lead implant attempt.
- Patient has an existing epicardial LV lead

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):	28-08-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	LV lead
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-07-2017
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	NL61223.100.17
Other	will follow later