Cognis and Teligen 100 HE & Reliance Quadripolar Defibrillation Lead (4-Site) Field Following

Published: 04-02-2008
Last updated: 11-05-2024

The purpose of this study is to evaluate and document that the clinical performance of the TELIGEN 100 HE and COGNIS 100 HE systems and associated application software is within design specifications. It will also document the appropriate clinical...

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON32376

Source
ToetsingOnline

Brief title
The Cogent-4 Field Following Study

Condition

- Cardiac arrhythmias

Synonym
Ventricular Tachyarrhythmia's - cardiac rythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: Guidant (Boston Scientific)

Intervention

Keyword: CRT-D, ICD, Quadripolar Defibrillation Lead, Reverse Mode Switch

Outcome measures

Primary outcome

The Device Specific Objectives of this study are to evaluate performance of all TELIGEN and COGNIS 100 HE devices as shown by documenting appropriate detection and shock conversion of induced ventricular tachyarrhythmia*s (VT/VF) at implant and/or pre-discharge. The RMS-Specific Objectives of this study are to evaluate appropriate performance of the Reverse Mode Switch (RMS) feature by documenting a 1-month RMS related Adverse-Event-Free-rate in TELIGEN 100 HE DR patients with the feature ON. And also to evaluate appropriate performance of the Reverse Mode Switch (RMS) feature by documenting a reduction in right ventricular pacing (Vp) with the feature ON versus OFF between the 1-month and 3-month visit. The Lead- Specific Objective of this study is to evaluate appropriate performance of the RELIANCE 4-SITE defibrillation lead by demonstrating appropriate pacing thresholds at follow-up.

Secondary outcome

To evaluate the performance of the Quick Convert ATP feature during normal clinical operation, to collect the number and appropriate function of Reverse Mode Switches during normal clinical operation, to collect and report percentage of BiV pacing in COGNIS 100 HE patients, to collect and report Respiration Rate Trend data, if available and to collect and report all adverse events including specifically all 4-SITE lead-related Adverse Events.

Study description

Background summary

The purpose of the study is to test a new family of Boston Scientific Implantable Cardioverter Defibrillators (*ICDs*) called the TELIGEN 100 HE ICD and the COGNIS 100 HE CRT-D. For some patients receiving the TELIGEN 100 HE ICD, there may also be a test of a new feature called *Reverse Mode Switch*. This new function is designed to safely limit the amount of pacing pulses that are sent to the right side of your heart so that it only provides pacing when you really need it. If available during the course of the study, a new type of lead called the RELIANCE 4-SITE lead will also be tested because it only has one pin to attach it to the device rather than the 3 pins used with older leads.

Study objective

The purpose of this study is to evaluate and document that the clinical performance of the TELIGEN 100 HE and COGNIS 100 HE systems and associated application software is within design specifications. It will also document the appropriate clinical performance of the 4-SITE defibrillation lead and associated quadripolar header configuration (if available within the timeline of the study). Moreover, the optional RMS sub-study will evaluate the clinical performance of the RMS feature in the TELIGEN 100 HE DR ICD.

Study design

This is a prospective and multi-centre study with data collected from a maximum of 450 patients at up to 50 study centres worldwide. The study consists of three patient groups. 1) For the device-related objectives are needed 150 patients at a minimum. 2) For the RMS sub-study are needed 110 patients at a minimum. 3) For the 4 SITE lead objectives are needed 150 patients at a minimum. Patients can participate to either one or more groups, so group 1) and/or 2) and /or 3). For group 1) and 2) there are two additional visits, namely at 1 and 3 months. Patients who participate to group 2) will have the RMS function from implantation till the 1 month visit, during which randomisation will determine whether the function will be on or off till the visit at month 3. Patients who only participate to group 3) will be followed by standard practice.

Study burden and risks

Burden : patients in group 1) and / or 2) require an additional visit at month 1 and 3.
Risk : the risks related to study participation are the same as when the

patient would not participate to the study.

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

Inclusion Criteria TELIGEN and COGNIS 100 HE:
• ICD Indication according to normal clinical practice (for those patients receiving a TELIGEN 100 HE)
• CRT-D Indication according to normal clinical practice (for those patients receiving a COGNIS 100 HE)
• Willing and capable of providing informed consent, undergoing a device implant, participating in all testing associated with this clinical investigation at an approved clinical investigational centre and at the intervals defined by this protocol
• Geographically stable patients who are available for follow-up at a study centre.

• Age 18 or above, or of legal age to give informed consent specific to national law
Reverse Mode Switch Sub-Study:
• Meet general inclusion/exclusion criteria for COGENT-4 study
• Implanted with TELIGEN 100 HE DR

Exclusion criteria

Exclusion Criteria TELIGEN and COGNIS 100 HE
• Documented life expectancy of less than six months or expected to undergo heart transplant within the next six months
• Patients currently requiring dialysis
• Women who are pregnant or plan to become pregnant. Method of assessment per physician discretion
• Enrolled in any concurrent study
• Patients implanted with the following leads which will not be abandoned:
- Atrial or right ventricular unipolar leads
- Patch defibrillation leads
- Non-compatible defibrillation leads (e.g. 5/6mm)
Reverse Mode Switch Sub-Study:
• Documented permanent/Complete AV block
• Documented permanent atrial fibrillation (AF)

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL20173.058.07