RELIANCE Quadripolar Defibrillation leads (4-site) Field Following

Published: 27-04-2009
Last updated: 04-05-2024

The purpose of this study is to evaluate and document appropriate clinical performance of the new RELIANCE Quadripolar (4-SITE) defibrillation lead and the 4-SITE Header / Lead interface when connected to the TELIGEN 100 HE 4-SITE (VR or DR)...

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

Summary

ID

NL-OMON33403

Source
ToetsingOnline

Brief title
The 4-SITE Field Following Study (4-SITE FF)

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: Boston Scientific

Intervention

Keyword: 4-SITE Header/Lead interface, Quadripolar Defibrillation lead, single connector Defibrillation lead

Outcome measures

Primary outcome

The primary objective of this study is to evaluate appropriate performance of the RELIANCE 4-SITE defibrillation lead and of the new 4-SITE Header / Lead interface by demonstrating - appropriate detection and shock conversion of induced Ventricular tachyarrhythmia*s (VT/VF)

-appropriate pacing thresholds, shock and pacing lead Impedances at follow-up as a measure of lead integrity over 12 month time, and - Appropriate sensing and absence of artefacts / non-sustained / sustained episodes resulting from transient potentials (artefacts) originating from incomplete lead / header contact.

Secondary outcome

The secondary objectives are to document Implant Experience by collecting and analyzing information regarding 4-Site system handling, and to answer clinical questions by performing different types of retrospective analysis of study data.

Study description

Background summary

The purpose of the study is to test a new lead: de RELIANCE quadripolar (4-SITE) defibrillation lead implanted together with an implantable 4-SITE cardioverter defibrillator (*4-SITE ICD*) from Boston Scientific: the TELIGEN

100 HE 4-SITE ICD (VR or DR) of the COGNIS 100 HE 4-SITE CRT-D.
The 4-SITE lead is special because it only has one pin to attach it to the device rather than the 3 pins used with previous style leads. This one pin contains all the functions from the previous lead type.

Study objective

The purpose of this study is to evaluate and document appropriate clinical performance of the new RELIANCE Quadripolar (4-SITE) defibrillation lead and the 4-SITE Header / Lead interface when connected to the TELIGEN 100 HE 4-SITE (VR or DR) implantable cardioverter defibrillator ICD, or the COGNIS 100 HE 4-SITE cardiac resynchronization therapy CRT-D.

Study design

This is a Prospective, multi-centre, field following study with data collected from a maximum of 450 patients at up to 50 study centres worldwide. Patients enrolled for the study will be followed for a period of 12 month after implant: at implant, pre-discharge (optional), 1, 3, 6, 9 and 12-months. It is estimated that the patient enrollment will be completed in approximately 9 months. The study is expected to start enrollment in Q2 of 2009. The total duration of the study is expected to be approximately 21 month.

Study burden and risks

Burden : patients require an additional visit at month 1, 3 and 9 months.
Risk : the risks related to study participation are the same as when the patient would not participate to the study.

Contacts

Public
Boston Scientific

Lambroekstraat 5D
1831 Diegem
BE
Scientific
Boston Scientific

Lambroekstraat 5D
1831 Diegem
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Study Specific
• ICD / CRT-D Indication according to normal clinical practice
- Patients receiving:
• a single or dual chamber 4-SITE compatible ICD
• or a 4-SITE compatible CRT-D
• one of the RELIANCE 4-SITE defibrillation leads
- Patients currently implanted with a pacemaker
• upgraded to a 4-SITE compatible ICD or CRT-D (4-SITE header)
• one of the RELIANCE 4-SITE defibrillation leads
General
• Willing and capable of providing informed consent for
• undergoing a 4-SITE system 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

Exclusion criteria

Study Specific
• ICD and CRT-D Patients scheduled for a device replacement
• CRM Patients who have or who would need an lead adaptor
• All patients who have an active or non-active defibrillation lead other than 4-SITE
General
• Not willing and not capable of providing informed consent, undergoing a device implant, participating in all testing associated with this clinical investigation (including VT/VF shock conversion) at an approved clinical investigational centre and at the intervals defined by this

protocol
• Patients who were in NYHA Class IV during the last 3 month
• Patients with pre-existing diseases, which may confound study results
• Patients currently requiring dialysis,
• Cancer patients
• Patients with drug and/or alcohol abuse history
• Life expectancy < 12 months (or expected heart transplant within 12 months)
• Patients on a Heart Transplant List
• Women who are pregnant or plan to become pregnant. Method of assessment per physician discretion.
• Enrolled in any other concurrent study

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	27-04-2009
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	NL27592.058.09