Left Ventricular Lead Acute Clinical Study

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

Summary

ID

NL-OMON34649

Source
ToetsingOnline

Brief title
LILAC

Condition

- Heart failures

Synonym
Heart Failure - Cardiac decompensation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: four electrodes, Left ventricular lead, over the wire, quad-polar

Outcome measures

Primary outcome

The primary objectives of this study is to characterize the electrical performance of a dual zone, quadpolar lead design in order to specify the electrode placement location on the spiral fixation of the lead body

Secondary outcome

The Secundary objectives of this study are to:

1. Evaluate the anatomic fit of the short and long straight tip leads

2. Measure the phrenic nerve stimulation threshold if it occurs during the pacing threshold testing and evaluate ability to mitigate PNS by switching pacing zones/locations

3. Evaluate the ability of the leads to be delivered and placed to the selected sites within the coronary branch veins using the standard CRT delivery tools and over-the-wire technique

Study description

Background summary

While recent advances in LV lead development now allow more flexibility in placing a lead inside the coronary vein tree to find the viable myocardial tissue and at the same time to avoid the phrenic nerve stimulation, the LV lead still requires acute repositioning at least one-third of the time during CRT implants. Left phrenic nerve stimulation continues to be the most common complication of intraoperative and perioperative transvenous lead placements. Despite attempts to avoid phrenic nerve stimulation during implant, it cannot always be completely prevented, and Electronic Repositioning has proven to than be an effective remedy.
The new lead design with the inclusion of four discrete electrodes is intended

to provide an implanting physician with a highly deliverable lead allowing multiple pacing configuration options to mitigate phrenic nerve stimulation and high thresholds.

Study objective

The primary purposes of this study is to characterize the optimal electrode placement and electrode spacing on the lead*s spiral fixation such that at least one electrode on the spiral will contact the myocardium site in the coronary vein.
Secondary purposes of this clinical investigation are to evaluate other acute pacing parameters including pacing impedance and sensing R-wave amplitude in multiple configurations; phrenic nerve stimulation threshold; anatomical fit of the different straight tip lengths; and handling characteristics of the new lead design.
The data generated in the acute human study will be used to make recommendations to the left ventricular (LV) lead product development project regarding the lead design factors mentioned above.

Study design

The LILAC study is an acute, non-randomized, multicenter data collection clinical investigation. All patients who are enrolled in the study undergo the same study testing. There is no patient control group required.
The total duration of the study is expected to be 12 months.

Study burden and risks

Burden: the lengthening of the total duration of the standard implant procedure by approximately 30 minutes
Risks:The major risks to the patients enrolled in this protocol are associated with the catheterization procedures, which is part of the standard LV lead implant procedures (see protocol page 31-32)
The risks associated with the lengthening of the total duration of the standard implant procedure by approximately 30 minutes are similar. The study testing will lead to a longer X-ray exposure.
Standard pacing threshold testing is part of any routine lead implant procedure. According to this protocol, additional threshold tests are performed, in order to characterize the lead design of three new prototypes. There is a risk of arrhythmia due to pacing threshold testing. Should an arrhythmia occur, the patient will be in a controlled clinical environment with specialized equipment and will be treated in accordance with standard procedures.
The risks associated with this trial are mitigated by the fact that no research devices will be permanently implanted in the patient and all components contacting the patient are sterile and used as per their individual

instructions for use.

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

• Patients who are scheduled to receive (new implant or upgrade) either CRT-P or CRT-D system based on physician discretion
• Patients who are scheduled to have an LV lead implantation based on physician discretion
• Patients who are expected to tolerate approximately 30 minutes of study testing procedures per physician discretion
• Patients who are willing and capable of providing informed consent, participating in all testing associated with this clinical investigation at an approved clinical investigational center
• Patients whose age is 18 years or above, or of legal age to give informed consent specific to state and national law

Exclusion criteria

• Patients who are allergic to the contrast media used in the study
• Patients who have a history of pocket or device related infection
• Patients who have any previous cardiac surgery within the last 3 months
• Patients who have concomitant cardiac surgery
• Patients who have unstable angina
• Patients who have myocardial infarction within the last 3 months
• Patients who are dependent on IV inotropes
• Patients who are in acute cardiac failure crisis
• Women of childbearing potential who are, or might be, pregnant at the time of the study (method of assessment upon physician*s discretion)
• Patients whose age is more than 80 years
• NYHA class IV patients
• Patients who are currently enrolled in another investigational study or registry that would directly interfere with the current study

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-10-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	quadrupolar LV lead
Registration:	No

Ethics review

Approved WMO Date:	14-09-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL31566.068.10