More Options available with a quadripolar LV lead provide in clinic solutions to CRT challenges

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Demonstrate that the usage of a quadripolar LV lead results in easier LV lead implantation procedure and less chronic LV lead related adverse events in comparison with a traditional biventricular left ventricle lead.

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

Summary

ID

NL-OMON39245

Source
ToetsingOnline

Brief title
MORE-CRT

Condition

- Heart failures

Synonym
Heart failure with dyssynchrony

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: Cardiac Resynchronisation Therapy, Heart failure, Phrenic nerve stimulation, Quadripolar lead

Outcome measures

Primary outcome

Survival from the composite endpoint of intra*operative and post*operative

endpoints.

Intra*operative LV lead related endpoint:

* Due to phrenic nerve stimulation, lead instability or high capture threshold:

o Changing to a different tributary vein of the coronary sinus following site

evaluation

o Using more than one LV lead during the procedure for any reason.

o Using any device (eg. a stent) to actively fixate the lead

* Unsuccessful implant for any reason

Post*operative:

Any serious adverse device effect (SADE) related to the LV lead

Abandoned CRT for any reason

Secondary outcome

* % of CRT responders (defined as patients with a reduction in LVESV of at

least 10% between

baseline and the 6*month follow*up visit)

* % of patients with % of Biventricular Pacing >90% at 6 months post implant

* Implant procedure duration (skin to skin)

* Implant fluoroscopy time

* Repositioning the lead within the same vein (following unsatisfactory lead

site evaluation)

* Final LV lead position

* Reprogramming of the LV output to <1V above the measured pacing threshold

* Improvements in Quality of Life (MLWHF, EQ*5D) between baseline (BASE) and at

6 months

follow up visit (6M FUP)

* Survival from HF hospitalizations at 6M FUP

* Survival from CRT system related hospitalizations at 6M FUP

* Survival from all cause mortality at 6M FUP

Study description

Background summary

Cardiac Resynchronisation Therapy (CRT) is a recognised and rapidly expanding therapy for heart failure (HF), it reduces death, HF hospitalisation and all cause mortality. Left Ventricular (LV) leads cannot be implanted in up to 10% of patients undergoing a
trans*venous system implantation. Even in studies that report a 96.5% success rate, there are 10.5% of patients that require multiple procedures before a lead is successfully implanted. These implant failures are not due to patient selection, but rather challenges posed by anatomy leading to lead stability problems, phrenic nerve stimulation and poor electrical measurements. Lead repositioning in the same
coronary sinus (CS) side*branch (in 26%) may be needed in case of poor lead stability, phrenic nerve stimulation (PNS) or unsatisfactory electric measurements(9) . 17% of leads can require a change from the first accessed vein to a second during the implant procedure due to unsatisfactory parameters. In many patients phrenic nerve stimulation is not identified until after the implant procedure, when movement and postural changes bring the pacing lead into closer contact with the phrenic nerve. Many can only be managed via a further invasive procedure (associated with a not insignificant infection risk) to reposition the lead and if this approach is not successful then a minor surgical procedure may be indicated to place a lead on the epicardial surface

of the heart. The Quartet® quadripolar electrode lead provides an opportunity to address implant challenges, such as phrenic nerve stimulation and unsatisfactory electrical measurements at implant, by programming pacing from one of 10 bipolar electrode configurations (rather than three) utilising one of the four lead electrodes as a pacing cathode. The increased programming possibilities provided by using a quadripolar electrode lead instead of traditional bipolar leads may provide non invasive alternatives in the management of these challenges, reducing time spent addressing the problems and the number of costly re*intervention procedures.

Study objective

Demonstrate that the usage of a quadripolar LV lead results in easier LV lead implantation procedure and less chronic LV lead related adverse events in comparison with a traditional biventricular left ventricle lead.

Study design

A prospective, randomized, open label, multicenter trial

Intervention

Implantation of a CRT-D device with a quadripolar LV Lead (treatment group) or with a traditional biventricular LV lead (control group).

Study burden and risks

The risk is comparable to the risk of a standard CRT-D implantation. In addition to the normal treatment patients will have a quality of Life questionnaire taken at baseline and at 6 month follow up which will require approximately 10-15 minutes extra time.

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 are indicated for CRT*D implantation, as per current international certified guidelines
- Patients age is 18 years or greater
- Patients must indicate their understanding of the study and willingness to participate by signing
the appropriate informed consent form
- Patients must be willing and able to comply with all study requirements

Exclusion criteria

* Patients with a life expectancy <12 months.
* Patients who are or may potentially be pregnant.
* Patient has suffered any of the following in the 4 weeks prior to enrolment.
o MI
o CABG
o Unstable Angina Pectoris
* Patient has primary valvular disease which has not been corrected

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2011
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	Biventricular ICD with quadripolar left ventricle lead
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-10-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	15-12-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	31-01-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	09-03-2012

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	11-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	14-09-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	19-07-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (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	NL37815.098.11