Strategic MAnagement to Optimize Response To Cardiac Resynchronization Therapy

Published: 06-03-2018
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The primary objective is to show the benefit of SmartDelay* in patients with a prolonged RV-LV interval.

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

Summary

ID

NL-OMON50579

Source
ToetsingOnline

Brief title
SMART CRT (0393/0028)

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac Resynchronization Therapy, Defibrillators, Heart failure, Medical device

Outcome measures

Primary outcome

There may be no additional benefit to the subject due to the study specific programming. However, medical science and future patients may benefit from their participation in this clinical study. If there is a superior or inferior arm, the subjects can be programmed at the conclusion of the study to the best programming suitable to their needs.

Secondary outcome

Not applicable

Study description

Background summary

SMART CRT is a prospective, double-blind, multicenter, international, randomized controlled trial. This study design helps assure that two comparable patient populations are obtained while mitigating bias such that any observed changes are due to the use of SmartDelay alone. The primary objective is to show the benefit of SmartDelay in patients with a prolonged RVLV interval defined as an increase in ejection fraction at 6 months compared to baseline. The RV-LV interval will be measured at the Post-Implant Assessment for all subjects enrolled and implanted with a BSC X4 CRT-D system. For those subjects identified with an RV-LV *70ms, 1:1 randomization will occur via the electronic data capture (EDC) system. Subjects will be randomized to have either an AV Delay and pacing chamber determined by SmartDelay or a Fixed AV Delay of 120ms with BiV pacing. Those subjects identified with an RV-LV < 70ms will be exited from the study after 30 day contact to assess for any reportable safety events. Commercially approved quadripolar Boston Scientific (BSC) Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices and future generations of BSC X4 CRT-D devices approved by the appropriate regulatory bodies will be included in the trial. All devices utilized in the study will include SmartDelay* and must be capable of providing SmartDelay recommendations for

both biventricular pacing (BiV) and Left Ventricular (LV) only pacing. Additionally, all CRT-D devices will utilize LV VectorGuide*. A commercially approved BSC Right Atrial (RA) lead and Right Ventricular (RV) lead are recommended to be included in this study, but any commercially available RA lead and RV lead from any manufacturer are eligible. Boston Scientific*s ACUITY* X4 IS4 heart failure lead family for the LV lead will be required.
The study will be conducted at up to 100 sites globally. An estimated 726 subjects will be enrolled in the study in order to achieve a target of at least 370 subjects to complete the Six Month Follow-Up.

Study objective

The primary objective is to show the benefit of SmartDelay* in patients with a prolonged RV-LV interval.

Study design

SMART CRT is a prospective, double-blind, multicenter, international, randomized controlled trial.

Intervention

One group that will have their CRT-D device programmed according to the SmartDelay algorithm
One group that will have their CRT-D device programmed according to a fixed timing interval of 120ms.

Study burden and risks

The implantable device systems and accessories used for this clinical study will be commercially available and are considered to be standard of care for patients indicated for such implants. The risks involved with subject participation in this study are essentially the same as those for patients not participating in the study.

There may be no additional benefit to the subject due to the study specific programming. However, medical science and future patients may benefit from their participation in this clinical study. If there is a superior or inferior arm, the subjects can be programmed at the conclusion of the study to the best programming suitable to their needs.

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

* Subject must be indicated to receive a de novo quadripolar Boston Scientific Cardiac Resynchronization Therapy Defibrillator (CRT-D) in conjunction with an ACUITY X4 LV lead. This includes subjects who are indicated to receive an upgrade to a BSC X4 CRT-D from a previously implanted device.
* In order to achieve a homogenous population for the study, qualifying subjects are those with heart failure who meet BSC US indications for use defined as those subjects who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:
o Moderate to severe heart failure (NYHA Class III-IV) with EF * 35% and QRS duration * 120 ms
o Left bundle branch block (LBBB) with QRS duration * 130 ms, EF * 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure
* Subject is age 18 or above, or of legal age to give informed consent specific to each country and national laws
* Subject is willing and capable of providing informed consent

* Subject is willing and capable of complying with visits and procedures as defined by this protocol

Exclusion criteria

* Subjects with documented permanent complete AV block
* Subjects with permanent or chronic atrial fibrillation (AF) or in AF at the time of enrollment
* Subjects who have previously received cardiac resynchronization therapy with pacing in the left ventricle
* Subjects on the active heart transplant list or who has or is to receive ventricular assist device (VAD)
* Life expectancy shorter than 12 months due to any medical condition (e.g., cancer, uremia, liver failure, etc*)
* Subject with a known or suspected sensitivity to dexamethasone acetate (DXA)
* Subject is enrolled in any other concurrent clinical study, with the exception of local mandatory governmental registries and observational studies/registries, without the written approval from Boston Scientific
* Women of childbearing potential who are or plan to become pregnant during the course of the trial
* Subjects currently requiring dialysis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2018
Enrollment:	12

Type:	Actual

Medical products/devices used

Generic name:	X4 quadripolar CRT-D device; ACUITY X4 quadripolar LV lead
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT03089281

Register	ID
CCMO	NL63340.029.17