Maximizing CRT Delivery by Using Multipolar Coronary Sinus Lead Family ACUITY X4

Published: 15-07-2014
Last updated: 20-04-2024

The objective of this study is to collect clinical data on safety and performance of ACUITY X4 leads when used outside a clinical trial in a standard clinical setting.

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON40761

Source
ToetsingOnline

Brief title
RALLY X4

Condition

- Heart failures

Synonym
CHF, heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CRT, lead, multipolar

Outcome measures

Primary outcome

Primary endpoints:

- PNS-related Complication-Free Rate (CFR) through 6 months post-implant

- Lead-related Complication-Free Rate (CFR) from Implant through 3 months post-implant

Secondary outcome

Secondary endpoints;

- All-cause mortality of the enrolled subject population

- Hospitalization rate due to decompensated heart failure in the enrolled subject population

- Lead related CFR from 3 months through 15 months post-implant

- LV-lead pacing threshold and electrical lead performance in mid to basal pacing position

- LV-lead pacing threshold and electrical lead performance for pre-specified / stipulated electrodes

- All-cause operative system revision

- Markers of LV remodelling: distal electrode sensing amplitude and Q-E1, Q-E2 delay

- All alerts which occurred in devices connected with LATITUDE will be compared with reported adverse events

- LATITUDE alerts and reported adverse events will be compared with recorded

diagnostic data which are available at the same time

Study description

Background summary

Implantation of pacing and defibrillation devices that provide cardiac resynchronization therapy (CRT) is a proven highly effective treatment for selected subjects with heart failure. Stable and accurate placement of a left ventricular lead is improves delivery success rate of CRT. The ACUITY family of leads, as compared to prior LV lead generations, provide the physician with additional lead placement flexibility and pacing performance choice due to their smaller size and variety of shapes and electrode spacing. These lead designs enable the pacing electrode to remain fixed in more proximal locations and the inclusion of 4 discrete electrodes allows for multiple LV pacing configurations. It is expected that this will lower the risk of phrenic nerve stimulation (PNS). It is also expected to mitigate against higher LV thresholds, which leads to more optimal battery longevity.

Study objective

The objective of this study is to collect clinical data on safety and performance of ACUITY X4 leads when used outside a clinical trial in a standard clinical setting.

Study design

This study is prospective, non-randomized, non-blinded observational multicenter study. Eight hundred to 1000 subjects will be enrolled in this study and followed for a maximum of 30 months. All study data will be collected during the regular standard of care patient visits.

Study burden and risks

This is an observational study. The patients will not be subjected to additional procedures, will not have to be interviewed or complete any questionnaires, and no specific conduct will be imposed on them, other than is necessary for the standard treatment of the patient. There will be no additional patient visits, the trial data will be collected during the regular visits to the hospital. Risks and burden for the patient will be the same as risks and burden for patients who receive similar treatment, outside of the study.

Contacts

Public
Boston Scientific Cooperation International

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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 is willind and capable of providing informed consent
- Subject is planned to be implanted with an ACUITY X$ lead for left-ventricular pacing and sensing via the coronary venous system in conjunction with a compatible BSC pulse generator
- Subject is willing and capable of participating in all visits associated with this study at an approved clinical study center and at the intervals defined by this CIP
- Subject os age 18 or above, or of legal age to give informed consent specific to state and national law

Exclusion criteria

- Subjects with a hypersensitivity to a maximum single dose of 0.51 mg dexamethasone acetate
- Subject is enrolled in any other concurrent study without prior written approval from BSC, with the exception of local mandatory governmental registries and observational studies/registries that are not in conflict and do not affect the following:
* schedule of procedures for the Rally X4 Study (i.e. should not cause additional or missed visits);
* Rally X4 Study outcome (i.e. involve medications that could affect the heart rate of the subject);
* Conduct of the Rally X4 study per GCP/ISO 14155:2011 / local regulations as applicable
- Per the implanting physician's discretion, the subject is not a sauitable candidate to receive the study device as determined during the implant procedure
- Women of childbearing potential who are or might be pregnant at the time of study enrollment
- Subject is unwillingor unable to participate in all scheduled study follow up visits at an approved study center
- Subject does not anticipate being a resident of the area for the scheduled duration of the trial
- Subject's physician does not allow participation

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:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	350
Type:	Anticipated

Medical products/devices used

Generic name:	leads for chronic left ventricular pacing
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-07-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	26-08-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL47828.075.14