Ingenio Device Algorithm Study

Published: 15-12-2011
Last updated: 28-04-2024

To gather data to support global submissions/approvals for some models of the Ingenio device family.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON35543

Source
ToetsingOnline

Brief title
IVORY

Condition

- Cardiac arrhythmias

Synonym
Pacemaker Therapy and Heart Failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Dual Chamber Pacemaker/CRT-P, Right Atrial Auto Threshold, RV pacing reduction

Outcome measures

Primary outcome

Effectiveness:

Right Atrial Automatic Threshold

1. Manual Unipolar vs. Commanded: Demonstrate the clinical equivalence of the commanded thresholds determined by the RAAT algorithm and the thresholds determined by the manual unipolar threshold tests.
2. Manual Unipolar vs. Ambulatory: Demonstrate the clinical equivalence of the ambulatory thresholds determined by the RAAT algorithm and the thresholds determined by the in-clinic manual unipolar threshold tests.
3. Appropriate Commanded RAAT Outcome: Demonstrate that the commanded RAAT threshold tests produce appropriate outcomes.

RYTHMIQ

4. Demonstrate a relative reduction of RV pacing with RYTHMIQ ON versus RYTHMIQ OFF.

Safety:

System-related complications (for FDA submission purposes)

5. Evaluate and document the System-related complications by assessing the SRCFR (without LV related events for CRT-P patients)

RAAT output margin

6. Demonstrate that the commanded RAAT threshold test produces a sufficient

pacing voltage output.

Safety parameters:

1. System-related complications

2. Percentage of RAAT tests resulting in a sufficient pacing output

Effectiveness parameters:

1. RAAT commanded test: Percentage of tests resulting in

a) an accurately-determined threshold

b) an appropriate test outcome

2. RAAT ambulatory tests: Percentage of tests resulting an

accurately-determined threshold

3. RYTHMIQ: % reduction in RV pacing (compared to RYTHMIQ OFF)

Secondary outcome

Not applicable

Study description

Background summary

Bradycardia therapy by means of implantable pacemakers is a well-established procedure for over 50 years. Worldwide the number of implants of pacemakers is steadily increasing. For outpatient clinics this poses an incremental burden. Therefore device manufacturers have developed automatic algorithms to lighten

this workload, like automatic capture for the ventricle. Subsequently research has been performed to introduce an automatic capture feature for the atrial channel and it was also introduced into clinical practice.

A high percentage of right ventricular stimulation can lead to a worsening of left ventricular function. Therefore avoiding needless right ventricular stimulation in patients with sufficient underlying ventricular activity seems beneficial and new pacemaker algorithms support this goal.

HF patient management aiming at preventing hospitalizations could have significant impact on patient care and economics. Given that an ever increasing number of HF patients have an implanted device, a potential exists for even greater benefits if the implanted device can be used to recognize signs of worsening HF since the implanted device has continuous access to the patient.

Study objective

To gather data to support global submissions/approvals for some models of the Ingenio device family.

Study design

Prospective, multi-center, randomized within-patient, single-blinded study

Intervention

Pacemaker/CRT-P implantation

Study burden and risks

Risks:
Subjects participating in this study are subject to the same risks shared by all patients undergoing implantation of a pacemaker or CRT-P system. Additional risks may exist.

Benefits:
There may be no benefit to the subject.
Subjects enrolled in this clinical evaluation may have some benefit from receiving the latest device technology since features within the implanted devices may provide some clinical benefit over existing models and technologies. The subject may also benefit from closer device follow-up due to the clinical protocol schedule.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects who are willing and capable of providing informed consent to undergo a device implant and to participate in all testing associated with this clinical study;;Subjects whose age is 18 or above.;Subjects indicated for a dual chamber pacemaker or a CRT-P device according to class I or class II indications of the standard ESC or ACC / AHA implant guidelines;;Subjects who are planned to be implanted with all leads intended for a specific device type (dual chamber pacemaker: atrial and right ventricular lead, CRT-P: atrial, right and left ventricular lead) or are already implanted with such leads;;Subjects who receive or are implanted with a bipolar atrial lead.

Exclusion criteria

Women of childbearing potential who are or might be pregnant at the time of the study (method of assessment upon physician*s discretion);;Enrolled in any other concurrent study, with the exception of local mandatory governmental registries and observational studies/registries that are not in conflict or affect
* Schedule of procedures for IVORY (i.e. should not cause additional or missed visits);
* Programming of devices for IVORY per CIP;
* IVORY outcome (i.e. involve medications, that could affect the heart rate of the subject);
* Conduct of IVORY per GCP / ISO 14 155:2011 / local regulations;;Subject who live at such a distance from the clinic that travels for follow-up visits would be unusually difficult or burdensome for the subject;;Inability or refusal to comply with the follow-up schedule;;A life expectancy of less than 12 months, per physician discretion;;Subjects who are planned to be programmed to a pacing mode other than DDD / DDDR during the study period.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Dual Chamber Pacemaker/CRT-P
Registration:	No

Ethics review

Approved WMO

Date:	15-12-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-02-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT01441583
CCMO	NL37760.098.11