Next Generation INCEPTA ICD and CRT-D Field Following Study: Respiratory Rate Trend Evaluation in Heart Failure Patients
NOTICE-HF

Published: 21-10-2010
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Study purpose I: To evaluate and document appropriate clinical performance of the INCEPTA (DR and VR) implantable cardioverter defibrillator (ICD) system and the INCEPTA cardiac resynchronization therapy ICD (CRT-D) system and associated application...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON34143

Source
ToetsingOnline

Brief title
NOTICE-HF

Condition

- Cardiac arrhythmias

Synonym
Ventricular Tachyarrhythmia's - cardiac rythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: GUIDANT Europe / BOSTON SCIENTIFIC

Intervention

Keyword: Heart Failure Patients, Next Generation INCEPTA ICD and CRT-D, Respiratory Rate Trend

Outcome measures

Primary outcome

Purpose I:

For purpose I, the appropriate clinical performance will be assessed by

evaluating and documenting:

• Sensing, impedance and threshold tests per applicable Reference guide

• All adverse events and all Product Experiences

• VT/VF detection & conversion if performed at implant or pre-discharge

• Spontaneous episode conversion

• Wanded and wireless telemetry

Performance will be compared with historical data.

Secondary outcome

Purpose II:

Changes in mean Daily median respiratory rate (*RR) between event (11-7 days

before an index time) and baseline (60-56 days before an index time).

Study description

Background summary

Next Generation INCEPTA ICD and CRT-D Field Following Study: Respiratory Rate Trend Evaluation in Heart Failure Patients

Study objective

Study purpose I:
To evaluate and document appropriate clinical performance of the INCEPTA (DR and VR) implantable cardioverter defibrillator (ICD) system and the INCEPTA cardiac resynchronization therapy ICD (CRT-D) system and associated application software.
Study purpose II:
Demonstrate the clinical relevance of chronic ambulatory daily median Respiratory Rate Trend (RRT) in HF patients

Study design

The study has two primary objectives, linked to the respective study purposes:
For purpose I:
The objective is to collect data on the performance of the INCEPTA ICD and CRT-D devices during standard clinical use at implant, pre-discharge and at a 1-month post-implant device evaluation.
For purpose II:
The objective is to show that daily median respiratory rate increases more in patients who experience an HF-event (Group 1) than in patients who do not experience an HF-event (Group 2). A comparison will be made between patients who experience an HF-event (Group 1) and patients who do not experience an HF-event (Group 2).

Intervention

ICD/CRT-D implantation

Study burden and risks

Risks:
Patients participating in this study are subject to the same risks shared by all patients undergoing implantation of an ICD or CRT-D system.
Benefits:
There may be no benefit to the patient.
Patients 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 patient may also benefit from closer device follow-up due to the clinical protocol schedule.

Contacts

Public
Boston Scientific

Lambroekstraat 5D
1831 Diegem
BE
Scientific
Boston Scientific

Lambroekstraat 5D
1831 Diegem
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients who are willing and capable of providing informed consent, undergoing a device implant, participating in all testing associated with this clinical study;
• Patients whose age is 18 or above, or of legal age to give informed consent specific to national law
• Patients indicated for an ICD according to normal clinical practice (for those patients receiving an INCEPTA ICD).
o As soon as 20 ICD patients are included in the study for purpose I, only NYHA Class III patients will be allowed in the study*. NYHA class should be documented in the last 3 months.
• NYHA Class III patients indicated for a CRT-D according to normal clinical practice (for those patients receiving an INCEPTA CRT-D). NYHA class should be documented in the last 3 months.

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.
• Inability or refusal to comply with the follow-up schedule
• Patients that have received routinely scheduled intravenous inotropic therapy as part of their drug regimen within the past 90 days
• Patients prescribed to positive airway pressure therapy
• A life expectancy of less than 1 year, per physician discretion
• Patient in NYHA Class IV during the last 4 weeks
• Patient who lives at such a distance from the clinic that travel for follow-up visits would be unusually difficult

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2010
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Next Generation INCEPTA ICD and CRT-D
Registration:	No

Ethics review

Approved WMO Date:	21-10-2010
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)
Approved WMO Date:	27-12-2010
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	NL32450.068.10
Other	wordt voor start studie geregistreerd bij www. clinicaltrials.gov