MICRA Transcatheter Pacing Study

Published: 16-09-2013
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See protocol page 12The purpose of this clinical study is to evaluate the safety and efficacy of the Micra Transcatheter Pacing system and to assess long-term device performance.

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

Summary

ID

NL-OMON38829

Source
ToetsingOnline

Brief title
MICRA

Condition

- Cardiac arrhythmias

Synonym
bradycardia, slow heart rate

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Leadless pacemaker, MICRA, Transcatheter

Outcome measures

Primary outcome

See protocol page 22-24, 84-95

Primary Objectives:

• Demonstrate that the freedom from acute major complications related to the Micra system and/or procedure at 6 months post-implant is greater than 83%

• Demonstrate that the percentage of subjects with an adequate pacing capture threshold at 6-months post-implant exceeds 80%.

Secondary outcome

See protocol page 24, 95-100

Secondary Objectives:

• Demonstrate the accuracy of Micra ventricular capture management pacing thresholds compared to manual pacing capture thresholds.

• Demonstrate the rate response operation of the Micra system.

Study description

Background summary

See protocol page 13, 14

Pacemaker treatment remains the only known, long term effective treatment for bradycardia. Since their introduction in the 1960s, pacemakers have steadily shrunk in size and grown in sophistication. Technology advances have now made it possible for Medtronic to develop a device small enough to implant within the heart while still providing similar battery longevity.
Conventional pacing systems consist of a pacemaker device and one or more leads

from the device pocket through veins into the heart. The Micra Transcatheter Pacing System is a miniaturized single chamber pacemaker system that is implanted directly inside the right ventricle of the heart, thereby potentially eliminating complications associated with traditional pacing systems.

Study objective

See protocol page 12

The purpose of this clinical study is to evaluate the safety and efficacy of the Micra Transcatheter Pacing system and to assess long-term device performance.

Study design

See protocol page 22

The Micra Transcatheter Pacing Study is a world-wide, multi-site, prospective, single-arm clinical trial.
After implant, subjects are followed at pre-hospital discharge, one month, three months, six months and every six months thereafter until official study closure (plan 5 years).
Up to 780 patents enrolled to implant 720 patients from up to 70 worldwide sites.

The study includes several analysis; CE analysis, interim analysis, final analysis, long-term analysis.

Intervention

- Implantation of a leadless single chamber pacemaker (Micra transcatheter Pacing System)

Study burden and risks

The risks are similar to those of a standard implantation of a single-chamber pacemaker. There are some risks that are not applicable for the Micra pacemaker such as problems associated with the lead and pocket. However, there are also a number of potential new risks associated with the implantation procedure and the Micra pacemaker;
- Vessel spasm
- Peripheral ischemia
- (psuedo) aneurysm
- Heart tissue damage due to fixation of the Micra
- Coronary arterial constriction

- Risk of arterio-venous fistula
- Device dislocation
- Device embolization

For an extensive overview see protocol page 75-79

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

Subjects who have a Class I or II indication for implantation of a single chamber pacemaker according to ACC/AHA/HRS 2008 guidelines and any national guidelines.

Exclusion criteria

Subjects who are entirely pacemaker dependent (escape rhythm <30 bpm).
**NOTE: After the 1st 25 usable 1-month holters, the steering committee will conduct a safety review and assess whether this criterion can be removed.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	MICRA Leadless pacemaker
Registration:	No

Ethics review

Approved WMO

Date:	16-09-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL45259.060.13
Other	Nog niet bekend