Candidate Predictors of Changes in Heart function

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31564

Source
ToetsingOnline

Brief title
MINERVA substudy

Condition

- Endocardial disorders

Synonym
Heart failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: heart failure, pacemaker, ventricular pacing

Outcome measures

Primary outcome

Heart function as measured with sensitive tissue/doppler echocardiography

(including Ejection fraction, right-left ventricular synchrony) and blood

values (BNP).

Secondary outcome

NYHA class (severity of symptoms)

Study description

Background summary

Clinical studies have shown that chronic pacing of the right ventricle can lead to atrial fibrillation and heart failure. The substudy proposes to i) investigate the changes in heart function over a period of 2 years after the start of pacing, and ii) map which factors can predict the development of heart failure in an early stage.

Study objective

The aim of the substudy is the identification of early (baseline) predictors of heart failure during a relatively high frequency of electrical stiumulation of the right ventricle. How does heart function change over a period of 2 years which patients are at the highest risk? This substudy investigates an extended set of physiological and clinical predictors. Results can contribute to improved pacing therapies with early intervention in heart failure.

Study design

Prospective, randomised, single blinded, multicenter study in which minimally 25 patients will participate. In the center that has agreed to participate in the substudy, all patients that have consented to participate in the Minerva main study will be randomly assigned at baseline to 1 of 3 study groups (Control/ MVP/ DDDRP group). The patients that are assigned to the control

group will be approached for participation in the substudy. This entails that the patient undergoes a number of additional measurements during follow ups for the Minerva main study. Blood sampling and tissue/doppler echocardio-graphy will take place during baseline, after 1 month, 3, 12 and every following 12 months until the end of the Minerva main study.

Intervention

Patients have an indication for a dual chamber pacemaker and will receive an Enrhythm device (irrespective of participation in the substudy). There will be no additional interventions in the substudy.

Study burden and risks

Patients will undergo a number of additional measurements during the follow-up visits in realtion to the Minerva main study. These additional measurements entail echocardiography (once) and blood sampling (3-4 times) which sums up to an extra 100 minutes.

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

1) Class I/II indication for dual chamber pacemaker
2) Previous implant of an Enrhythm dual chamber pacemaker since max 2 weeks
3) Documented history of atrial arrhythmias in last 12 months
4) Randomised assignment to control group in the Minerva main study

Exclusion criteria

- Younger than 18 years
- History of permanent atrial fibrillation
- Candidates for implantable defibrillator (ICD) or Cardiac Resynchronization Therapy (CRT)
- Permanent AV block or AV-node ablation
- Anticipated major cardiac surgery within the course of the study
- Random assignment to DDDRP group or MVP group

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-05-2008
Enrollment:	10

Type:	Actual

Medical products/devices used

Generic name:	Pacemaker
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-02-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL20183.094.07