Optimal Sensing in Atrial Tachyarrhythmia's Study

Published: 25-03-2010
Last updated: 04-05-2024

Verification of number of mode switches, Verification of undersensing of AFor other ATAs. Incidence of mode switches due to FFRW oversensing using Accent pacemaker in the most sensitive sensing setting(s)using the Optisense vrs Tendril lead

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

Summary

ID

NL-OMON38036

Source
ToetsingOnline

Brief title
OSAT

Condition

- Cardiac arrhythmias

Synonym
atrial tachyarrhythmia, Atrium fibrillation, palpitations

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical Nederland BV

Intervention

Keyword: AF sensing, Automatic Mode Switch, Far Field R-Wave, Optisense Lead

Outcome measures

Primary outcome

• Number of mode switches due to FFRW oversensing

• Number and duration of inappropriate modeswiches due to FFRW sensing during sinus rhythm

• Number of episodes and total duration of paroxysmal AF and AT from Holter recording

• Number of and total duration of undersensing of paroxysmal AF and AT in pacemaker.

• Number of 2:1 lock-in during AT or Aflutter.

Secondary outcome

• Sensing of myopotentials

Study description

Background summary

For patients with indications for chronic cardiac pacing who suffer from atrial arrhythmias, the pacemaker therapy is based on data about these arrhythmias stored in the pacemaker memory. If therapy is based on PM data, the automatic mode switching (AMS) algorithm has to function reliable for the identification of the onset and offset as well as the incidence and duration of paroxysmal atrial rhythm disturbances such as AF and AT (ATA's). The reliability of AMS depends on adequate sensing and discrimination of atrial potentials. Inappropriate mode switching during the detection of ATAs is caused by sensing of far field signals most frequently by sensing the far field R-wave (FFRW) signals. The lead characteristics have proved to be a determining factor in the sensing of the FFRW. A shorter spacing between the dipole (tip to ring) of a bipolar lead makes the pacemaker system less susceptible to FFRW sensing. A

recent experimental study*s demonstrated that FFRW can be reduced effectively without loss of P wave amplitude, i.e. with maintenance of the P-wave/FFRW ratio, with a novel lead designed with a short tip ring distance of 1.1 mm. Consequently, a lead with a similar tip-ring distance is now commercially available and approved for clinical use and will be compared to a more conventional lead in its ability to avoid oversensing of FFRW's while preventing undersensing of atrial fibrillation. In other words the new lead is less sensible to the disturbing FFRW signals but can it still recognize AF?

Study objective

Verification of number of mode switches, Verification of undersensing of AFor other ATAs. Incidence of mode switches due to FFRW oversensing using Accent pacemaker in the most sensitive sensing setting(s)using the Optisense vrs Tendril lead

Study design

Prospective, singleblind, 1:1 randomised study comparing a group with Optisense leads with a group with Tendril leads.

Intervention

Implantation of an Accent pacemaker according to the routine implantation procedure for pacemakers.

Study burden and risks

There is a limited chance of experiencing palpitations during the first 3 day Holter recording due to the sensitive settings of the pacemaker. The burden of these palpitations will be limited.

Contacts

Public
St. Jude Medical

Standaardruiter 13
3905 PT Veenendaal
NL
Scientific
St. Jude Medical

Standaardruiter 13

3905 PT Veenendaal
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients with class I or II pacing indications for Sick Sinus Syndrome with suspected paroxysmal atrial tachyarrhythmias over the 6 months.
• Signed informed consent
• Age >18 yrs

Exclusion criteria

• Left Ventricular Ejection Fraction <35% (last 6 months)
• Severe valvular heart disease
• Congestive heart failure - NYHA class III - IV
• Angina Pectoris class III-IV
• Hypertrophic Cardio-myopathy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2010
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	Pacemaker with Optisense of Tendril 1888/1788 lead
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-03-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-06-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-07-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-08-2010
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-08-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-02-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-03-2012
Application type:	Amendment
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
ClinicalTrials.gov	NCT01074749
CCMO	NL29728.100.09