Right Atrial Pacing versus Left Atrial Pacing to Prevent Development of Paroxysmal Atrial Fibrillation in Patients with Sick Sinus Syndrome or Anti-arrhythmic Drug-induced Bradycardia.

Published: 16-10-2012
Last updated: 26-04-2024

- To determine the effects of the pacing site on prevention of AF episodes - To examine the relation between the pacing site, reduction of AF episodes, quality of life, heart failure, number of cardioversions, frequency and duration of hospital...

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

Summary

ID

NL-OMON39873

Source
ToetsingOnline

Brief title
Riverleft

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
incidental atrial fibrillation, Paroxysmal atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Biotronik Nederland bv,Riverleft commissie

Intervention

Keyword: Bradycardia, LAS, Pacing, PAF

Outcome measures

Primary outcome

Primary endpoint of this study is development of paroxysmal atrial fibrillation

despite left or right atrial stimulation.

The follow up period is 36 months. At specific time intervals patient will be

called by the investigator in order to check whether atrial fibrillation has

occurred. Patients atrial rhythm will continuously be monitored by Home

Monitoring® supplied by the pacemaker manufacturer.

Secondary outcome

Quality of Life assessment will be performed at specific time intervals.

Study description

Background summary

Rationale:

The Sick Sinus Syndrome (SSS) is defined as an intrinsic, symptomatic form of sinus node dysfunction.
It is caused by damage to either the sinus node itself, surrounding nerves and ganglia or the atrial myocardial
by e.g. inflammation, fibrosis or fatty infiltration.
To our knowledge, the incidence of paroxysmal atrial fibrillation (PAF) in patients with SSS is unknown.
It has been estimated that 40 to 50% of patients with a pacemaker have sinus node disease.

Studies have reported various incidences (8.2% and 45.5%) of PAF in patients with SSS.
Prescribed anti-arrhythmic drug therapy for PAF might induce bradycardia.

The number of AF episodes in SSS patients may be reduced by pacing in the atria.
Preventive pacing inhibits AF by averting sinus bradycardia or by suppressing premature beats.

In a recent pilot study, Breuls et al. demonstrated that left atrial stimulation was more effective than right atrial stimulation in terms of reduction of AF episodes and improvement in quality of life in SSS patients with paroxysmal AF.

Hypothesis:

In patients with the Sick Sinus Syndrome or anti-arrhyhmic drugs-related bradycardia, overdrive pacing from the left atrium is more effective than from the right atrium in preventing AF paroxysms.

Study objective

- To determine the effects of the pacing site on prevention of AF episodes
- To examine the relation between the pacing site, reduction of AF episodes, quality of life, heart failure, number of cardioversions, frequency and duration of hospital admission, AF progression and cardiac death.
- To study electrical remodeling by analyzing characteristics of AF episodes obtained from continuously cardiac monitoring of atrial rhythm.

Study design

This is a multi-center, randomized, prospective study and will be performed between October 2014 and October 2019.
Patients of the participating hospitals will be recruited at the department of cardiology.
When pacemaker implantation is indicated and paroxysms of atrial fibrillation are documented, patients will be asked to participate in this study.

Intervention

Patients will get a pacemaker implanted and the pacemaker lead will either be placed near the left atrium (coronary sinus) or in the right atrium (right atrial appendage).

Study burden and risks

Besides pacemaker implantation risks in general, there are no specific study related risks. Due to lead implantation in the coronary sinus, rupture of this structure is possible. Therefore a pericardial puncture is slightly more likely.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Written informed consent signed by patient
- Sick Sinus Syndrome or anti-arrhythmic drug-induced bradycardia
- Documented paroxysmal atrial fibrillation with a duration of >= 30 seconds in the past 6 months
- 18 years old or older

Exclusion criteria

- Life expectancy of <= 5 years
- Left Ventricular Ejection Fraction of <= 40 percent
- Congenital Heart Defects
- Mentally unable to participate in the follow up protocol
- Physically unable to participate in the follow up protocol
- Malignancies
- Chronic Obstructive Pulmonary Disease (COPD)
- GFR value of <= 30 mL/min or Creatinine value of >= 250 umol/l
- Participation in another investigational drug or device study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2013
Enrollment:	330
Type:	Actual

Medical products/devices used

Generic name:	Pacemaker
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-12-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-10-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-02-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ISRCTN	ISRCTN65911661
CCMO	NL38970.078.12