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RIght VERsus LEFT study: treatment of paroxysmal atrial fibrillation in patients with sick sinus syndrome: Right atrial stimulation versus left atrial stimulation

Submission date
11/06/2013

Recruitment status
No longer recruiting

Registration date
08/07/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
When the heart beats, the heart muscle contracts (pulls inwards) in preparation for pumping blood around the body. The contractions are produced by electrical pulses. These are generated by a group of specialised cells known as the sinoatrial node (SA node). In sick sinus syndrome, the SA node no longer works as it should. This can lead to an abnormally slow heartbeat, an abnormally fast heartbeat or, in some cases, a combination of both. To our knowledge, the incidence of paroxysmal atrial fibrillation (a heart condition that causes an irregular and often abnormally fast heart rate which comes and goes and usually stops within 48 hours without any treatment) in patients with sick sinus syndrome is unknown. The number of atrial fibrillation (AF) episodes in sick sinus syndrome patients may be reduced by pacing in the atria (placing pacemaker which sends regular electrical pulses that help keep the heart beating regularly). Preventive pacing inhibits AF by averting sinus bradycardia (slow heartbeat) or by suppressing premature beats. The objectives of the study are:
1. To determine the effects of the pacing site on prevention of AF episodes
2. To examine the relationship between the pacing site, reduction of AF episodes, quality of life, heart failure, number of cardioversions [medical procedure by which an abnormally fast heart rate (tachycardia) or cardiac arrhythmia is converted to a normal rhythm], frequency and duration of hospital admission, AF progression and cardiac death.
3. To study electrical remodeling by analyzing characteristics of AF episodes obtained from continuous cardiac monitoring of atrial rhythm.

Who can participate?
Male and female, 18 years old or older patients with the sick sinus syndrome and paroxysms of AF will be included.

What does the study involve?
Patients of the participating hospitals will be recruited at the department of cardiology. The investigator is responsible for patient selection and appropriate inclusion. Each patient, prior to

enrolling in the study, will be provided with a written explanation of the study procedure together with an assessment of risks in participating in the study. Written informed consent will be obtained from all patients. No patient will be enrolled if the consent form is not signed. The informed consent form will also be signed by the investigator. Patients will get a pacemaker implanted and the pacemaker lead will either be placed near the left atrium or in the right atrium (atrium - the four chambers in the heart). The follow up period is 36 months. At specific time intervals patient will be called by the investigator in order to check whether AF has occurred. Patients atrial rhythm will be continuously monitored.

What are the possible benefits and risks of participating?
Left atrial pacing has the potential benefit to prevent recurrence of paroxysmal AF. Besides pacemaker implantation risks in general, there are no specific study-related risks. Due to lead implantation in the atrium, rupture of this structure is possible.

Where is the study run from?
Participating medical centers in the Netherlands.

When is the study starting and how long is it expected to run for?
The study will take place between November 2012 and November 2017

Who is funding the study?
Rijnmond Society of Cardiology, Netherlands

Who is the main contact?
T.T.T.K. Ramdjan, PhD candidate in the Erasmus Medical Center Rotterdam, The Netherlands t. ramdjan@erasmusmc.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL38970.078.12

Study information

Scientific Title
RIght VERsus LEFT study: treatment of paroxysmal atrial fibrillation in patients with sick sinus syndrome: Right atrial stimulation versus left atrial stimulation - a randomized controlled trial

Acronym
RIVERLEFT

Study objectives
In patients with sick sinus syndrome and paroxysmal atrial fibrillation, pacing from the left atrium is more effective than from the right atrium in preventing AF paroxysms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved on October 16th 2012 by the medical ethics committee in the Erasmus Medical Center Rotterdam, The Netherlands, Ethics reference no: NL38970.078.12

Study design
Multicenter randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiology / preventive pacing / sick sinus syndrome

Interventions

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).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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.

Follow up visits will be planned 1, 3, 6, 12, 18, 24, 30 and 36 months after pacemaker implantation.

Secondary outcome measures
Quality of life assessment will be performed at follow up visits 1, 3, 6, 12, 18, 24, 30 and 36 months after pacemaker implantation.

Overall study start date
01/11/2012

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. Male and female, 18 years old or older
2. Written informed consent signed by patient
3. Sick sinus syndrome
4. Documented paroxysmal atrial fibrillation with a duration of less than 30 seconds in the past 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
572

Key exclusion criteria
1. Life expectancy less than 5 years
2. Left ventricular ejection fraction of less than 40%
3. Congenital heart defects
4. Mentally unable to participate in the follow-up protocol
5. Physically unable to participate in the follow-up protocol
6. Malignancies
7. Chronic obstructive pulmonary disease (COPD)
8. GFR value of less than 30 ml/min or creatinine value of less than 250 umol/l
9. Participation in another investigational drug or device study

Date of first enrolment
01/11/2012

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
's Gravendijkwal 230
Rotterdam
Netherlands
3015 CE

Sponsor information

Organisation
Erasmus Medical Center (Netherlands)

Sponsor details
c/o F. Zijlstra, MD, PhD
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Other

Funder Name
Rijnmond Society of Cardiology (Cardiologen Club Rijnmond) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/11/2014		Yes	No