ISRCTN67629267 https://doi.org/10.1186/ISRCTN67629267

A study evaluating the effects of Selective Site Ventricular Pacing on the haemodynamic and functional recovery of patients following atrio-ventricular nodal ablation

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 10/04/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0054174158

Study information

Scientific Title

Study objectives
1. The principal purpose of this study is to investigate whether pacemaker leads positioned at the outflow tract of the right ventricles close to the Purkinje fibre improves patient's exercise capacity and cardiac function as compared to the traditional right ventricular apex pacing site
2. The secondary objectives of this study are to investigate whether pacing at the right ventricular outflow tract position as compared with the traditional right ventricular apex site:
2.1 Improves quality of life
2.2 Prevents the recurrence of irregular heart beats
2.3 Achieves better directed blood flow through the heart pumping chambers
2.4 Reduces occurrence of heart failure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Surgery: Atrio-ventricular nodal ablation

Interventions
Our hypothesis is that better patient's exercise capacity and recovery of cardiac pumping function can be achieved by positioning the pacing leads at the site where blood flows out of the right lower pumping chamber of the heart commonly described as the right ventricular outflow tract (RVOT) compared with the traditional position of right ventricular tip or apex RVA site). One of the biggest problems with the interpretation of these studies in the past has been the heterogeneity (mixed disease states) of the patients recruited and the variation in their requirements for pacing. The study will recruit only patients with similar clinical outlook or disease state to ensure a homogenous population that requires similar constant ventricular pacing. This unique cohort will be recruited following the removal of defective natural pacemaker (A-V nodal ablation) during the treatment for persistent irregular heartbeats (atrial fibrillation/flutter). A single chamber rate-responsive pacemaker will be implanted with leads in the RVA or RVOT position. The RVA will be defined as the most inferior and lateral l position providing acceptable pacing parameters in the right anterior oblique view. The RVOT will be defined as a position below the pulmonary valve and above a line drawn parallel to the RV inferior border, extending from the apex of the tricuspid valve (His) to the border of the right ventricle in an antero-posterion view, with acceptable pacing parameters. Patients ill then be allocated to one of the two types of pacemaker site settings by the toss of a coin (randomised) using a computer programme. 50% of patients will be chosen to undergo RVA pacing and the other 50% will undergo RVOT pacing. The pacemaker will be programmed according to standard

clinical practice on an individualised patient basis. All other aspects of the procedure and subsequent care will be as per our routine practice for pacemaker implantation. All participants in this study will undergo transthoracic echocardiography (heart ultrasound scan) and exercise test before implantation, at 6, 12 and 24 months after the procedure to evaluate how the pacemaker is affecting their heart function and general physical fitness. A total of 80 patients will be recruited and the investigator will be responsible for screening all patients listed for AV nodal ablation on clinical grounds. The patients selected for participation will be part of the investigators general patient population meeting the indications for the use of a permanent pacemaker system. The patients will be randomised and included in the study if they meet the inclusion criteria and give informed written consent. The initial screening will consist of a single transthoracic echocardiogram, a simple exercise test with non-invasive measurement of cardiac output and Quality of Life questionnaires. The echocardiogram will be performed in standard views by an experienced member of staff with full Accreditation from the British society of Echocardiography. The exercise test will be performed on a cycle ergometer using a standard ramp protocol with second by second measurement of respiratory gases. Blood pressure will be measured at standard intervals using a calibrated sphygmomanometer and a 12-lead electrocardiogram monitored throughout. Cardiac output (the amount of blood pumped out of the heart at each cycle) will be measured at rest and during peak exercise using validated rebreathing methods described in the literature. The Cardiothoracic Centre is a stand-alone tertiary cardiac centre providing high quality electrophysiological services to the 2.8 million population of Cheshire, Merseyside, North Wales and the Isle of Man. There is confirmed full support for this study by all the other consultants in this clinical field and the patients service users research awareness group.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
The primary endpoints of functional capacity as measured by Peak VO2 (ml, kg, min) and exercise time (sec) (or 28-day), Peak Cardiac Output (l, min) and Peak Cardiac Power Output (watts) will be evaluated by categorical outcome measures using a Pearson's Chi-square test or Fisher's exact test as required. Continuous variables will be examined using a 2-sided unpaired t-test or a non-parametric equivalent. All tests will be evaluated at a significance level of 5%.

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/11/2007

Eligibility

Key inclusion criteria
It has been estimated that a total of 80 patients will be required for this initial study (allowing for 7-15% drop outs, deaths etc). This was estimated using a two sided alpha of 0.05, and an 80% power to detect a 10% change in peak VO2 from a baseline of 20 ml/kg/min assuming a standard deviation of 4 ml/kg/min (20%). A total of 80 patients will be recruited and the investigator will be responsible for screening all patients listed for AV nodal ablation on clinical grounds. The

patients selected for participation will be part of the investigators general patient population meeting the indications for the use of a permanent pacemaker system. The patients will be randomised and included in the study if they meet the inclusion criteria and give informed written consent. All patients who fulfill the eligibility criteria will be approached by the principal investigator. A patient information sheet will be provided. Only patients who provide written informed consent prior to the procedure will be included. A copy of the written consent will be stored in the medical records, the study file and a copy will be given to the patient. The investigator will sign in the case record form that informed written consent has been obtained and the date consent was obtained. Informed consent will involve individual discussion with the patient about the nature of the procedures in a language that is easy to comprehend. The potential risks and benefits will be explained to the patient and they will be given time to make a decision about participation. It will be made clear that there is a random allocation to the two groups (RVOT versus RVA selective site pacing) and the patient or the physician does not decide which group they are allocated. It will be made clear that the patient can withdraw at any time from the research and does not have to give an explanation and it will not affect their medical care in any way. It will be recommended that if possible the patient is given 24 hours to think about participation and discussing with family, friends or other healthcare professionals before signing the consent form.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Indication for implantation of implantable cardioverter defribillator (ICD) because the heart is beating too fast or use of biventricular pacemaker
2. Evidence of left or right bundle branch block or QRS > 120 ms
3. Exercise limitation due to a pathological process e.g angina, respiratory, neurological or rheumatological disease
4. Significant valvular heart disease including indwelling prosthesis
Current or recent participation in any other clinical investigation
5. Life expectancy less than 6 months
6. Patient inability to independently comprehend the patient information sheet or sign the consent form

Date of first enrolment
01/11/2005

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Cardiology
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust

Funder Name
NHS R&D Support Funding

Results and Publications

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?
Results article	results	01/12/2009		Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes