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Dual site versus single site irrigated tip catheters in the ablation of atrial flutter

Submission date
27/03/2009

Recruitment status
Stopped

Registration date
20/04/2009

Overall study status
Stopped

Last Edited
30/07/2013

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Catheter ablation is a procedure that is used to carefully destroy a diseased area of the heart and interrupt abnormal electrical circuits. This study is designed to compare three different types of catheter commonly used to perform ablations for atrial flutter (abnormal heart rhythm). In particular we are interested to know whether cooling the tip of the catheter by sprinkling water through it (irrigation) at two sites rather than one makes it more effective.

Who can participate?
Male or female patients aged 18 years or above who are having an ablation procedure to prevent or treat atrial flutter.

What does the study involve?
Patients will be randomly allocated to be treated with one of the three catheters. We will record how long the procedure takes, how much energy we need to give and how long we X-ray you for.

What are the possible benefits and risks of participating?
There are no direct benefits to you of taking part in this study. Hopefully our findings will help select the best catheter design for future patients. There are no additional risks to you of taking part in this study above and beyond the risks of the procedure. Catheter ablation is associated with a risk of damage to blood vessels, damage to structures within the heart and leaving people needing a pacemaker afterwards. Sometimes the treatment does not work and people go on experiencing arrhythmias. The ablation procedure is carried out under the guidance of X-rays which deliver a small radiation dose. Partly for this reason this is not a procedure which should normally be carried out if you are pregnant.

Where is the study run from?
John Radcliffe Hospital (Oxford, UK).

When is the study starting and how long is it expected to run for?
The study is expected to run from June 2009 to January 2011.

Who is funding the study?
The study is sponsored by the Oxford Radcliffe Hospitals NHS trust.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09/H0605/7

Study information

Scientific Title
A randomised controlled trial of dual site versus single site irrigated tip catheters in the ablation of atrial flutter

Study objectives
That a difference may exist in catheter abaltion of atrial flutter using an ablation catheter with a dual ring of irrigation ports versus that with a single ring.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design
Three-arm multicentre randomised 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
Atrial flutter

Interventions
Study design:
A single blind 1:1:1 randomisation schedule by means of site specific sealed envelope system controlled by study administrator.

Study procedures:
Patients deemed by an electrophysiologist to be indicated to undergo a cavotricuspid isthmus ablation will be randomised by a site specific sealed envelope system to one of the three catheters. The ablation will be performed with coronary sinus and right atrial multipolar catheters, whilst recording radiofrequency lesion time, fluoroscopy time and procedure time. Conduction time will be assessed in both directions between proximal coronary sinus and the low right atrial free wall at 600 msec paced cycle length pre- and post-block (unless the patient is in atrial flutter at the start of the case in which case this will be assessed after termination of flutter only). Recurrence during a 30 minute post ablation wait time will be recorded as an event and additional time after this included in the final totals. Diagnostic catheters used and any mapping system used will be recorded.

Study treatment:
All participants will be undergoing clinically indicated cavotricuspid isthmus ablation.

Duration of study:
Participation will be from consent until follow up between three and four months post procedure. We expect to recruit all the patients within a twelve month period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Radiofrequency time to cavotricuspid isthmus block, time from when ablation starts to when the procedure is deemed complete.

Secondary outcome measures
1. Fluoroscopy time to cavotricuspid isthmus block, the amount of x-ray screening time needed for the primary endpoint to be achieved
2. Total procedure time, includes all time, i.e., not only the primary endpoint time but any additional time of the procedure before and after

Overall study start date
01/06/2009

Completion date
01/01/2011

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Patient/subject or legal representative is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Diagnosed with atrial flutter

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
63 patients

Key exclusion criteria
Pregnancy

Date of first enrolment
01/06/2009

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiac Department
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
John Radcliffe Hospital
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United Kingdom
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Sponsor type
Hospital/treatment centre

Website
http://www.oxfordradcliffe.nhs.uk/home.aspx

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded (UK)

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