

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

Submission date 27/03/2009	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/04/2009	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/07/2013	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
Dr Kim Rajappan
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Contact information

Type(s)
Scientific

Contact name
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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 ablation 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

Headley Way

Headington

Oxford

England

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