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Catheter versus thoracoscopic surgical ablation in long standing persistent atrial fibrillation

Submission date
22/04/2015

Recruitment status
No longer recruiting

Registration date
24/04/2015

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a heart condition that can result in an irregular and abnormally heart rate. Many people do not have any symptoms and are not aware they have the conditions. Others may sometimes feel dizzy, become short of breath, feel very tired and become aware of a fast and irregular heart beat (palpitations). The main complication of AF is an increased risk of stroke. Patients are often treated with anticoagulants to help prevent stroke and treatments to help restore a normal heart rhythm and heart rate. There are two key aspects of treatment for AF. The first is protection from stroke, which is done with blood thinning medications. Treatment of the heart rhythm can focus on controlling the rate (frequency of contraction) or controlling the rhythm (managing the regularity of contraction). Rate-control is generally employed first with an intent to reduce the rate at which the lower pumping chambers contract and improve their efficiency. Appropriate medication is used and with this treatment strategy it is accepted that AF will be present as the long term heart rhythm. If symptoms persist despite medication the preferred strategy is to restore sinus rhythm (SR) and regular contraction in all pumping chambers of the heart. This can be done with electric shock treatment (DC cardioversion) together with long-term tablet medication (this is usually a temporary measure), or by a more definitive 'cauterisation' therapy (catheter or thoracoscopic surgical ablation). In this study we will be looking at patients with symptomatic long standing persistent AF (i.e. those who have had continuous AF for more than 1 year) who have tried and failed tablet and/or electrical therapy, and thus require rhythm control with a more definitive ablation procedure. At present we do not know what the best ablation technique is for treating symptomatic, long-standing persistent AF (LSPAF). Catheter ablation (CA) is the current invasive treatment available for AF. Thorocoscopic surgical ablation (SA) is not widely available but our hospitals have the expertise to conduct this procedure. CA has been shown to achieve modest degrees of success in restoring normal SR with the caveat that most patients do require 'multiple' treatments (usually two or three). SA offers patients an alternative choice of therapy with a keyhole surgical approach. It may have a higher single procedure success rate although there is the potential for greater complication rates. We aim to examine this in detail to help us understand which approach might be better.

Who can participate?
Adults (aged at least 18) with LSPAF.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 (surgical group) are given minimally invasive thoracoscopic surgical AF ablation under general anaesthesia. Those in group 2 (control group) are given the standard catheter ablation treatment. After surgery, all participants receive the usual care according to standardised hospital protocol. Each participant is also given a implantable loop recorder (ILR) during surgery which then allows heart rhythm monitoring for 12 months. All participants are followed up every 3 months until 12 months after surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Royal Brompton and Harefield NHS Foundation Trust (UK) and Liverpool Heart and Chest NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
Recruitment will run from August 2015 to June 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Matthew Gill

Contact information

Type(s)
Scientific

Contact name
Mr Matthew Gill

Contact details
Royal Brompton & Harefield NHS Foundation Trust
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

NCT02755688

Secondary identifying numbers
18834

Study information

Scientific Title
CAtheter versus thoracoscopic Surgical Ablation in long standing persistent atrial fibrillation: a multicentre randomised controlled trial

Acronym
CASA-AF

Study objectives
The aim of this trial is to compare the efficacy of thoracoscopic surgical ablation with catheter surgical ablation for the treatment of longstanding persistent atrial fibrillation (AF).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford A, 05/03/2015, ref: 15/SC/0023

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Arrhythmia

Interventions
The study will compare outcomes in two groups of patients: one group will undergo catheter and the other surgical ablation of areas giving rise to atrial fibrillation.

1. Thoracoscopic Surgical AF Ablation:
Patients randomised to the surgical arm will receive minimally invasive thoracoscopic surgical AF ablation under general anaesthesia. Transesophageal echocardiography will exclude left atrial thrombus in order for the procedure to progress. Three small chest openings on each side of chest will allow insertion of a radiofrequency clamp which will produce a standardized set of heat leasions on the outer surface of the left atrium. Following completion of the procedure the patients will be managed according to standardised hospital protocol.

2. Catheter AF Ablation:
Patients randomised to the control arm will receive catheter AF ablation preceded by transoesophageal echocardiography to exclude left atrial thrombus. This procedure is also carried out under general anaesthetic and involves insertion of a long catheter via peripheral vascular system. A standard set of radiofrequency lesions is applied to the outer surface of the left atrium using the catheter. Following catheter ablation patients will be managed post-operatively according to the usual hospital protocols.

Patients will have an implantable loop recorder (ILR) inserted at the end of both interventions to allow post-procedure heart rhythm monitoring for 12 months. Furthermore, patients will have detailed follow-up at 3 monthly intervals until 12 months post-procedure.

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary efficacy end-point is freedom from atrial arrhythmias after a single procedure without AADs at 12 months

Secondary outcome measures
Previous secondary outcome measures:
1. Intervention-related major complication rate defined as permanent injury or death, that requires intervention for treatment, or prolongs or requires hospitalization for more than 48 hours
2. Clinical success, defined as a 75% or greater reduction of AF burden assessed by implantable loop recorder at 12 months with or without AADs.
3. Freedom from atrial arrhythmia, after multiple procedures without AADs at 12 months
4. Atrial anatomy and function following ablation as assessed by echocardiography and CMR
5. Change in AF symptom score (EHRA score) and quality of life assessments (EQ5D, AFEQT)
6. Quality Adjusted Life Years (QALYs) accrued during the 12-month study period
7.Cost-effectiveness (Incremental Cost per QALY gained) for surgical ablation compared with CA estimated over the 12-month study period ('within trial' analysis) and over a lifetime horizon (estimated by modeling)

Current secondary outcome measures as of 22/03/2017:
1. Intervention-related major complication rate defined as permanent injury or death, requires unplanned intervention for treatment, or prolongs or requires unplanned hospitalization for more than 48 hours
2. Clinical success, defined as a 75% or greater reduction of AF burden assessed by implantable loop recorder at 12 months with or without AADs.
3. Freedom from atrial arrhythmia, after multiple procedures without AADs at 12 months
4. Atrial anatomy and function following ablation as assessed by echocardiography and CMR
5. Change in AF symptom score (EHRA score) and quality of life assessments (EQ5D, AFEQT)

6. Quality Adjusted Life Years (QALYs) accrued during the 12-month study period
7.Cost-effectiveness (Incremental Cost per QALY gained) for surgical ablation compared with CA estimated over the 12-month study period ('within trial' analysis) and over a lifetime horizon (estimated by modeling)

Overall study start date
01/01/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. LSPAF (> 12 months' duration)
3. EHRA > 2
4. Left ventricular ejection fraction ≥ 40%
5. Suitable for either ablation procedure (added 05/05/2016)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
120

Key exclusion criteria
Exclusion criteria as of 05/05/2016:
1. Valvular heart disease with severity greater than mild
2. Contraindication to anticoagulation
3. Thrombus in the left atrium despite anticoagulation in therapeutic range
4. Cerebrovascular accident within the previous 6 months
5. Previous thoracic or cardiac surgery (including surgical interventions for AF)
6. Prior left atrial catheter ablation for AF
7. Unable to provide informed written consent
8. Active malignancy, another severe concomitant condition or presence of implanted

intracardiac devices that would preclude patient undergoing study specific procedures
9. Pregnant or breast-feeding, or women of childbearing age not using a reliable contraceptive method

Previous exclusion criteria:
1. Significant valvular heart disease
2. Contraindication to anticoagulation
3. Thrombus in the left atrium despite anticoagulation
4. Cerebrovascular accident within the previous 6 months
5. Significant previous thoracic or cardiac surgery (including surgical interventions for AF)
6. Prior left atrial catheter ablation for AF
7. Unable to provide informed written consent
8. Active malignancy or another severe concomitant condition that would preclude patient undergoing study specific procedures
9. Pregnant or breastfeeding, or women of childbearing age not using a reliable contraceptive method

Date of first enrolment
30/06/2015

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton and Harefield NHS Foundation Trust (lead trust)
London
United Kingdom
SW3 6NP

Study participating centre
Liverpool Heart and Chest NHS Foundation
United Kingdom
L14 3PE

Sponsor information

Organisation

Royal Brompton & Harefield NHS trust

Sponsor details
Sydney Street
London
England
United Kingdom
SW3 6NP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the study will be published in peer reviewed journals and presented at conferences. We will also disseminate the findings to participants at the end of the study.

Intention to publish date

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/02/2018		Yes	No
Results article	results	14/12/2020	02/09/2020	Yes	No
Results article		01/10/2021	19/05/2023	Yes	No
HRA research summary			28/06/2023	No	No