

A randomised comparison of cardioversion and catheter cryoablation in patients with persistent atrial fibrillation

Submission date 04/12/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/06/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Persistent atrial fibrillation (AF) is the most common sustained heart rhythm disorder and is associated with a variety of symptoms including lethargy and breathlessness. This can be treated with cardioversion with long-term medication, or a more definitive treatment with ablation. The usual first line treatment for persistent AF is cardioversion but recurrence rates following this are up to 90%. The aim of this study is to determine whether cryoablation is more effective than cardioversion at preventing recurrence of persistent AF.

Who can participate?

Patients aged over 18 with persistent AF who are suitable for cryo catheter ablation

What does the study involve?

Participants are randomly allocated to one of two groups. Group 1 undergo AF ablation with pulmonary vein isolation using cryoablation. Cryoablation is a minimally invasive procedure and has a success rate of between 57-69% in treating persistent AF. The procedure involves passing two tubes into a vein from the groin. After crossing to the left chamber of the heart (atrium), a balloon is used to engage the pulmonary veins which are then frozen. The procedure lasts around 90 minutes. Group 2 undergo cardioversion, which involves a controlled electric shock to the chest wall under general anaesthesia or heavy sedation. This is usually performed as a day case procedure. Participants are followed up with three clinic visits 3, 6 and 12 months later, along with a 24-hour Holter monitor to assess symptoms and medication review as well as a telephone interview at 9 months. All patients are provided with and trained to use a home monitor to send weekly ECGs and further ECGs at times of symptoms. Patients are also asked to complete questionnaire forms at the beginning and end of the study.

What are the possible benefits and risks of participating?

Depending on the group participants are allocated to, taking part in this study may involve exposure to ionising radiation through x-ray imaging. This will occur if participants are in the cryoablation group (not cardioversion). The cryoablation procedure may or may not be considered part of normal standard of care. Participant's local study centre will be able to advise

on whether this is the case.

The dose of radiation from this procedure could be up to 7.4 mSv. This represents a total lifetime cancer risk of about 1 in 1400 for females aged between 20 and 29 years (the risk reduces for older patients and is lower for male patients). This compares to a natural baseline lifetime risk of getting cancer in the UK of about 1 in 3. This dose of radiation is equivalent to about 3.4 years of natural background radiation to which we are all subjected. As this is an invasive procedure, there are risks associated with it. These risks are small but include bleeding and vascular problems (1%), phrenic nerve damage (1%), stroke (0.25%), pericardial effusion (2%) and death (0.1%). There are no additional risks in taking part in the study. During the study and ablation procedure, there will be a full complement of catheter laboratory staff present who are fully trained to deal with urgent medical situations. The risks of cardioversion include superficial burns and chest discomfort. It is important that participants remember to take their anticoagulation medication to minimize the risk of stroke.

Where is the study run from?

1. Brighton and Sussex University Hospitals NHS Trust (UK)
2. Portsmouth Hospitals NHS Trust (UK)
3. University Hospital Southampton NHS Foundation Trust (UK)
4. East Sussex Healthcare NHS Trust (UK)
5. Leeds Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2017 to September 2021

Who is funding the study?
Medtronic (USA)

Who is the main contact?
Duncan Fatz, duncan.fatz@nhs.net

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

36582

Study information

Scientific Title

Randomised controlled trial of cryoablation versus cardioversion in persistent atrial fibrillation

Acronym

CHILLY-AF

Study objectives

The aim of this study is to determine whether cryoablation is more effective than cardioversion at preventing recurrence of persistent atrial fibrillation (AF).

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of England – Essex Research Ethics Committee, 01/12/2017, ref: 17/EE/0448

Study design

Randomised; Interventional; Design type: Treatment, Complex Intervention

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 to request a patient information sheet

Health condition(s) or problem(s) studied

Atrial fibrillation

Interventions

The study is a randomised comparison of cardioversion (DCCV) to catheter cryoablation in patients with persistent atrial fibrillation (AF).

Prior to intervention participants will have a physical examination, electrocardiogram and routine blood tests. Participants will be started on an antiarrhythmic medication and randomised to either a cardioversion or a cryoablation, which will continue for 6 weeks after the intervention. A cardioversion involves a "jump-starting" the heart under sedation or general anaesthesia. The procedure takes around 20 minutes. The cryoablation procedure involves freezing around the pulmonary veins using a balloon (cryoballoon) and measurement of electrical signal around the veins to ensure it has been successful. The procedure lasts around 90 minutes.

Patients will then be followed up with three clinic visits at 3, 6 and 12 months from intervention, along with a 24-hour Holter monitor to assess symptoms and medication review as well as a telephone interview at 9 months. All patients will be provided with and trained to use a home monitor to send weekly ECGs and further ECGs at times of symptoms. Patients will also be asked to complete questionnaire forms (EQ-5D-5L and AFEQT questionnaires) at the beginning and end of the trial.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Time to event analysis of first recurrence of atrial arrhythmia measured 90 days after index procedure: documented arrhythmia recurrence (atrial fibrillation, flutter or tachycardia), >30 seconds on Holter at 3, 6 and 12 months, sustained arrhythmia on hand held ECGs
2. Safety endpoint: composite of death from any cause and serious adverse events during the study based on patient history and medical records

Timepoint(s): Duration of the study

Secondary outcome measures

1. Death from any cause, death from arrhythmia, first rehospitalisation for cardiovascular causes, total number of hospitalizations for cardiovascular causes during the study based on patient history and medical records
2. Time to recurrent atrial fibrillation (any time), time to symptomatic atrial fibrillation is measured using either 24 hour Holter monitor or hand-held ECGs
3. Quality of life is measured using the EQ-5D-5L and AFEQT questionnaires at baseline and 12 months

Overall study start date

01/08/2017

Completion date

24/09/2021

Eligibility

Key inclusion criteria

1. First presentation of persistent atrial fibrillation
2. Suitable for cryo catheter ablation
3. EHRA (European Heart Rhythm Association) Class 2 or higher after optimal rate control

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 150; UK Sample Size: 150

Total final enrolment

150

Key exclusion criteria

1. Renal failure with creatinine > 200 µmol/L or on dialysis
2. Pregnancy: current or currently planning
3. Previous ablation for atrial fibrillation
4. Previous DC cardioversion
5. Current participation in another clinical trial
6. Sinus rhythm at screening

Date of first enrolment

01/02/2018

Date of final enrolment

30/09/2019

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Brighton and Sussex NHS Hospitals (lead centre)**

Royal Sussex County Hospital

Eastern Road

Brighton

United Kingdom

BN2 5BE

Study participating centre

University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre

Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre

Leeds Teaching Hospitals NHS Trust
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre

East Sussex Healthcare NHS Trust
Eastbourne District General Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Sponsor information**Organisation**

Brighton and Sussex University Hospitals NHS Trust

Sponsor details

Royal Sussex County Hospital
Eastern Road
East Sussex
Brighton
England
United Kingdom
BN2 5BE

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Industry

Funder Name

Medtronic

Alternative Name(s)

Medtronic Inc.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/07/2022

Individual participant data (IPD) sharing plan

Individual participant data that underlie the results reported in the current study, after de-identification (text, tables, figures, and appendices) and Study Protocol, Statistical Analysis Plan, Analytic Code will be available upon request beginning 3 months and ending 5 years following

article publication. The data will be available to researchers who provide a methodologically sound proposal. Proposals should be directed to james.mccready@bsuh.nhs.uk. To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			23/06/2023	No	No
HRA research summary			28/06/2023	No	No