ISRCTN10910054 https://doi.org/10.1186/ISRCTN10910054

Wall thickness in the upper chamber of the heart and its effect on heart rhythm disorders

Submission date
15/11/2016

Recruitment status
No longer recruiting

Registration date
15/11/2016

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a common heart condition affecting around 2% of the UK population. When a patient suffers from AF the atria (upper chambers in their heart) stop pumping. This alters the heart rhythm, and can make the heart beat quickly and erratically. It happens because the electrical signals that normally control the atria are disturbed. AF usually begins as short 'stop – start' episodes lasting minutes to hours. Gradually these episodes become longer and occur more frequently. AF is a serious condition that can cause stroke and heart failure. Patients with AF are more likely to be admitted to hospital, have a lower life expectancy and can experience severe symptoms. Drugs designed to prevent AF are frequently ineffective and can be dangerous, so procedures that negate or reduce the need for drug treatment are of great importance. Catheter ablation (CA) is a surgical technique which is used to destroy the areas of the heart which are sending out the irregular signals. In the procedure, a thin flexible tube (catheter) is inserted into a major artery in the groin and guided up to the heart. The tip of the catheter then burns (radiofrequency ablation) the affected areas. This procedure is often very successful, and can completely cure AF in some cases. Variation in the thickness of the atrial wall is a significant cause of CA treatment failure. No tool exists to measure wall thickness throughout the atrium. Such a tool would provide the operator with information regarding the necessary – and safe - amount of cauterisation to apply in different areas. The research team has developed a technique to measure atrial wall thickness from computed tomography (CT or 'CAT') scans which provides a map of atrial wall thickness in three dimensions. The aim of this study is to find out how well this tool is able to measure atrial wall thickness in patients with AF who are planned for CA procedures, compared to those who are not.

Who can participate?
Adults with AF who have an AF/AT ablation planned and adults of the same age who have been referred to have a CT scan and have no history of AF.

What does the study involve?
Patients with AF undergo a CT scan to assess the thickness of their left atrial wall. In addition, they wear a 24 hour heart monitor and have a cardiac magnetic resonance (CMR) scan (a type of heart scan) as part of their normal care. Those who undergo CA have these tests repeated and answer a questionnaire about their health and current symptoms one year later.

Patients without AF undergo a CT scan as part of their usual care. In addition, they wear a 24 hour heart monitor and have a cardiac magnetic resonance (CMR) scan (a type of heart scan) as part of their normal care. The results of these tests are then compared to the patients with AF.

What are the possible benefits and risks of participating?
The additional imaging will provide additional information about heart structure that would not be available otherwise and in some cases may be valuable. Heart rhythm monitoring in the patients without AF may identify asymptomatic (symptomless) heart rhythm disorders. There are no notable risks associated with participating.

Where is the study run from?
St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2015 to April 2018

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr John Whitaker
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Contact information

Type(s)
Public

Contact name
Dr John Whitaker

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MRJBAER

Study information

Scientific Title
Left atrial wall thickness assessment using cardiac computed tomography and its impact on electrophysiology

Acronym
CT-LAWT

Study objectives
Tissue thickness of the left atrium is different in patients who suffer with atrial fibrillation from those who have no heart rhtyhm disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Westminster Research Ethics Committee, 30/12/2015, ref: 15/LO/1803

Study design
Single-centre observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
Patients with AF will undergo a cardiac computed tomography scan (CCT) to assess left atrial wall thickness. As part of their routine clinical care they will under cardiac magenetic resonance (CMR) scanning and 24 hour heart rhythm monitoring. Participants are followed up after one year and are asked to complete a structured questionnaire. If participants undergo AF ablation within the first year the electrical measurements will be repeated at this point.

Control participants consist of those those who have been referred for CCT to exclude coronary artery disease. They will undergo additional CMR scanning and 24 hour heart rhythm monitoring. This will allow a comparison of wall thickness as calculated from CCT and atrial tissue characterisation from CMR to be compared between the study and control group. There is no additional follow up.

Intervention Type
Other

Primary outcome measure
1. Tissue thickness in the left atrium in patients and controls is measured using cardiac computed tomography (CCT) at baseline
2. Firbosis and sphericity in patients and controls is measured using cardiac magenetic resonance (CMR) at baseline

Secondary outcome measures
1. Recurrence of rhythm disturbance within patients is measured using ambulatory ECG monitoring at 12 months as part of routine clinical care
2. Tissue characteristics of patients with recurrence and those without recurrence of AF in the patient group are measured using cardiac magenetic resonance (CMR) at baseline

Overall study start date
01/10/2015

Completion date
01/04/2018

Eligibility

Key inclusion criteria
Cases:
1. Between the ages of 18 and 75
2. Capable of giving informed, written consent in English
3. Planned for a first clinically indicated ablation procedure for atrial fibrillation/tachycardia
4. Planned for AF/AT ablation under general anaesthetic

Controls:
1. Between the ages of 18 and 75
2. Capable of giving informed, written consent in English
3. Have a clinical indication for cardiac CT (CCT)
4. No history of AF

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
40

Total final enrolment
25

Key exclusion criteria
1. Patient is not able or willing to provide written, informed consent in English
2. Patient does not meet all of the inclusion criteria
3. Patient is enrolled in another clinical trial that involves an extension of the duration of the AF ablation procedure
4. Patient has a contraindication to adequate cardiovascular computed tomography imaging including but not limited to body habitus, implanted material and iodine based contrast allergy
5. Patient has a contraindication to adequate cardiac magnetic resonance imaging including but not limited to body habitus, implanted material, claustrophobia and gadolinium based contrast allergy
6. Patient has chronic kidney disease stage with an estimated glomerular filtration rate of below 50ml/min (in whom there is greater conferring an additional risk of developing contrast induced nephropathy following CCT and CMR imaging)
7. Patient has an implantable cardiac electrical device
8. Patient is female and of childbearing potential (to reduce the excess risk associated with radiation exposure in this group)
9. Patient has any of the following comorbidities:
9.1. Moderate or severe valvular stenosis or regurgitation
9.2. Hypertension of more than 10 years duration, or not adequately controlled with 2 or fewer anti-hypertensive agents
9.3. Left ventricular hypertrophy with maximum LV wall thickness greater than 15mm
9.4. Hypertrophic cardiomyopathy
9.5. Left ventricular failure with ejection fraction less than 40%

Date of first enrolment
01/10/2016

Date of final enrolment
04/01/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
Jennifer Boston
R&D Department
16th Floor, Tower Wing
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SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Organisation
King's College London

Sponsor details
Keith Brennan
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SE1 4UL

Sponsor type
University/education

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of study results in a high impact peer reviewed journal when he data collection and analysis are complete.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
Models produced of atrial wall thickness and segmentations will be made available on http://www.cardiacatlas.org/.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/07/2021	09/08/2021	Yes	No
HRA research summary			28/06/2023	No	No