ISRCTN11704185 https://doi.org/10.1186/ISRCTN11704185

Electrical assessment of cardiac chambers

Submission date 15/11/2016	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 15/11/2016	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 15/11/2016	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a heart rhythm disorder that affects up to 2% of the population and is associated with stroke, heart failure and death. The disease is caused by a disturbance in the electrical activity within the heart. Over the past 18 years treatment for AF has expanded dramatically, following crucial observations about the areas in one of the upper chambers of the heart (the left atrium) where the heat rhythm disturbance begins. While the origin of AF is now much better understood, the processes by which the abnormal rhythm continues remains less well understood. This has limited the development of more successful treatments for AF and at present, those patients with the 'persistent' form of the condition have a significantly lower success rate when they are treated than those with the earlier, stop-start from of the condition (paroxysmal AF). The aim of this study is to take electrical measurements from within the chambers of the heart affected in this, and related, heart rhythm disorders in order to better understand the processes that allow them to persist. In the future it is hoped that this will result in more effective treatment for these conditions.

Who can participate?
Adults who are undergoing surgery to treat a heart rhythm disorder (such as AF) as part of their normal care.

What does the study involve?
After enrolment in the study, all participants undergo an RFA procedure as part of their standard care. This is a commonly used treatment for AF, which involves a thin flexible tube (catheter) being inserted through a major artery and guided up to the heart, where it burns the damaged area of the heart away using radiation. At the time of the RFA procedure a series of additional electrical measurements (extending the procedure by no more than 30 minutes) are taken. At the end of their RFA procedure the participants involvement with the study is complete.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating, although it is hoped that the knowledge gained from taking these measurements will be directly relevant to patients with heart rhythm disorders in the future.

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 October 2019

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Dr John Whitaker
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Contact information

Type(s)
Public

Contact name
Dr John Whitaker

Contact details
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London
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Additional identifiers

Protocol serial number
EPStim

Study information

Scientific Title
Programmed cardiac stimulation to measure electrophysiological function

Acronym
EP Stim

Study objectives
The aim of this study is to develop and refine protocols for the invasive assessment of cardiac electrophysiological properties.

Ethics approval required
Old ethics approval format

Ethics approval(s)

South East Coast - Surrey Research Ethics Committee, 30/11/2015, ref: 15/LO/1889

Study design
Observational cross sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Heart rhythm disorders

Interventions
At the time of clinically indicated electrophysiology study a series of additional electrical measurements will be made using clinically approved equipment and restricted to the cardiac chambers to which access is required for the clinical procedure.

Intervention Type

Primary outcome(s)
Cardiac conductivity and refractoriness will be assessed using analysis of recorded electrograms recorded at the time of the clinically indicated electrophysiology study.

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Between the ages of 18 and 85
2. Capable of giving informed, written consent in English
3. Undergoing a clinically indicated electrophysiology study or atrial fibrillation ablation procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 EP study or AF ablation procedure
4. Patient is a female and of childbearing potential

Date of first enrolment
26/01/2016

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
United Kingdom

England

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

Organisation
King's College London

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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?
HRA research summary			28/06/2023	No	No