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

# Electrical assessment of cardiac chambers

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| **Submission date**<br>15/11/2016 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>15/11/2016 | **Overall study status**<br>Completed | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>15/11/2016 | **Condition category**<br>Circulatory System | [ ] Individual participant data<br>[ ] 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
john.whitaker@kcl.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Dr John Whitaker

### Contact details
Fourth Floor North Wing
St Thomas' Hospital
Division of Imaging Sciences & Biomedical Engineering & Cardiac Electrophysiology
King’s College London
Westminster Bridge Road
London
United Kingdom
SE1 7EH

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Cross sectional 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
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 measure
Cardiac conductivity and refractoriness will be assessed using analysis of recorded electrograms recorded at the time of the clinically indicated electrophysiology study.

## Secondary outcome measures
No secondary outcome measures

## Overall study start date
01/10/2015

## 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
100

### 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
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**
Research & Development Department
16th Floor, Tower Wing
Great Maze pond
London
England
United Kingdom
SE1 9RT

**Sponsor type**
Hospital/treatment centre

**Organisation**
King's College London

**Sponsor details**
Director of Research Management
Director of Administration (Health Schools)
Room 1.8 Hodgkin Building, Guy's Campus
King's College London
London
England
United Kingdom
SE1 4UL

**Sponsor type**
University/education

**Organisation**
Guy's and St Thomas' NHS Foundation Trust

**Sponsor details**

**Sponsor type**
Not defined

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

**ROR**
https://ror.org/00j161312

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Heart Foundation

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

**Funding Body Type**
Private sector organisation

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

**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**
01/10/2020

**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 |