Electrical assessment of cardiac chambers

Submission date	Recruitment status No longer recruiting	Prospectively registered		
15/11/2016		<pre>Protocol</pre>		
Registration date	Overall study status	Statistical analysis plan		
15/11/2016 Last Edited	Completed Condition category Circulatory System	Results		
		Individual participant data		
15/11/2016		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

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