

Producing heart cells from patients with inherited heart rhythm disorders from skin cells in order to develop new treatments

Submission date 04/02/2015	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/02/2015	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/08/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Inherited Arrhythmia Syndromes (IAS) are caused by changes (mutations) in the genetic make-up of the heart (genes form the pattern of molecules within cells that are inherited from our parents). Heart cells are electrically charged, like a battery so any changes in the make-up of the cell (gene mutations) can cause disruptions to the rhythm of the heart. The heart beat can become irregular (arrhythmia) and sometimes it can stop completely, leading to death. Studying living heart cells is very difficult but this study hopes to take advantage of a new technique that allows scientists to obtain heart cells from samples of skin taken from patients with IAS. The cells obtained from such samples are similar enough to the cells of the heart muscle it is possible to study to effect of the mutations on the electrical properties of the heart. We can determine the cause of arrhythmias and sudden death and then test new therapies within a laboratory. Ultimately this will increase our understanding of IAS and lead to targeted treatments.

Who can participate?

Adult patient with confirmed diagnosis of inherited condition OR family member of patient with inherited condition

What does the study involve?

Collection of sample tissues.

What are the possible benefits and risks of participating?

The benefit is increased understanding of IAS leading to the development of new treatments. There are no risks, other than slight discomfort associated with obtaining a skin biopsy.

Where is the study run from?

Central Manchester NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

From April 2015 to March 2017

Who is funding the study?
University of Manchester

Who is the main contact?
Dr Luigi Venetucci
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Contact information

Type(s)
Scientific

Contact name
Dr Luigi Venetucci

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1; 09/02/2015

Study information

Scientific Title
Use of cardiac myocytes derived from skin fibroblasts to study patients with Inherited Arrhythmia Syndromes (IAS)

Study objectives
Discovery science - no hypothesis

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Prospective tissue sample and data collection

Primary study design

Interventional

Secondary study design

Tissue sample

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet**Health condition(s) or problem(s) studied**

Inherited Arrhythmia Syndromes

Interventions

Skin biopsy in order to derive cardiac cells

Intervention Type

Procedure/Surgery

Primary outcome measure

Derivation of cardiac myocytes from skin fibroblasts obtained from patients affected by inherited arrhythmia syndromes and their family members.

Secondary outcome measures

1. Identification of new genes in patients with inherited arrhythmia syndromes
2. Testing of new treatment strategies for inherited cardiac conditions

Overall study start date

01/04/2015

Completion date

30/03/2017

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility**Key inclusion criteria**

1. Confirmed diagnosis of inherited condition OR family member of patient with inherited condition

- 2. Aged > 18
- 3. Informed consent available

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

- 1. Unwilling or unable to give informed consent
- 2. Age <18

Date of first enrolment

01/04/2015

Date of final enrolment

30/03/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Central Manchester NHS Foundation Trust

Manchester Royal infirmary

Grafton Street

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

University of Manchester

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/027m9bs27>

Funder(s)**Funder type**

University/education

Funder Name

University of Manchester

Alternative Name(s)

The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

Plan to publish in high impact peer-reviewed journals of Cardiology but this is unlikely to be before 2017.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

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