ISRCTN25297151 https://doi.org/10.1186/ISRCTN25297151

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

Registration date
13/02/2015

Overall study status
Stopped

Last Edited
03/08/2018

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
luigi.venetucci@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Luigi Venetucci

Contact details
Institute of Cardiovascular Sciences
University of Manchester
Core Technology Facility
Grafton Street
Manchester
United Kingdom
M13 9NT
+44 (0)161 275 1202
luigi.venetucci@manchester.ac.uk

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)

RES Committee North West - Greater Manchester Central, 29/04/2015, ref: 15/NW/0301

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 Arrhthymia 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
3.53 Simon Building
Oxford Road
Manchester
England
United Kingdom
M13 9PL
+44 (0)161 275 8795
fmhsethics@manchester.ac.uk

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