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HCMR - Novel Predictors of Outcome in Hypertrophic Cardiomyopathy

Submission date 22/10/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/10/2014	**Overall study status** Completed	
Last Edited 10/04/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01915615

Protocol serial number
16889

Study information

Scientific Title
HCMR - Novel Predictors of Outcome in Hypertrophic Cardiomyopathy

Acronym
HCMR Study

Study objectives
Hypertrophic cardiomyopathy (HCM) is a condition, mostly inherited, in which the heart muscle becomes thickened. People with this condition usually do not have symptoms. However, in some people with this condition, there is a risk of developing complications such as failure of the heart to pump blood and sudden death. Currently doctors do not know much about why some people develop these complications. The purpose of this study is to find ways of predicting the risk of developing these problems, so that appropriate treatment can be given. This study will carry out a careful and thorough assessment of people with HCM using new sophisticated tests to identify markers that are associated with these complications. This information will help doctors to identify people with HCM who are at higher risks of developing complications in the future as a result of the disease.

The University of Oxford, UK, in collaboration with the University of Virginia, US are organising this research. The research taking place in Europe is the responsibility of the University of Oxford, while that taking place in North America is the responsibility of the University of Virginia. There will be 40 sites involved in this study as follow:

1. UK: 11 sites
2. Germany: 3 sites
3. Italy: 4 sites
4. The Netherlands: 2 sites
5. USA: 17 sites
6. Canada: 3 sites

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/SC/0190; First MREC approval date 20/05/2014

Study design
Non-randomised; Interventional; Design type: Prevention

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
1. Cannula and venous blood sampling (~80mls);
2. Medical history and physical examination
3. Echocardiogram. Ultrasound images of the heart using standard clinical scanners. This will only be done if there is no echocardiogram done in the last 12 months.
4. Electrocardiogram (ECG). Attaching surface electrodes on the chest to monitor electrical

properties of the heart. This will only be done if there is no ECG done in the last 12 months.
5. Cardiovascular magnetic resonance (CMR) imaging of the heart acquired using standard clinical scanners.
6. Gadolinium contrast dye injected via a cannula in the participant's arm to enhance images during MRI scans.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The composite of cardiac death due to sudden cardiac death (SCD) and congestive heart failure (CHF)

Key secondary outcome(s))
1. Aborted SCD including appropriate intracardiac defibrillator (ICD) firing
2. Need for heart transplantation

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Male or Female, aged 18-65
2. Established diagnosis of HCM defined as unexplained LVH defined as any segment = 15mm thick
3. Signed informed consent
4. Able (in the investigator's opinion) and willing to comply with all study requirements;

1300-1500 recruited in the Europe, of which 600-1000 recruited in the UK. A further 1250 will be recruited in the US and Canada and these sites have sought and received separate IRB approvals in the US and Canada.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Uncontrolled hypertension as judged by the investigator
2. Atrial fibrillation at time of enrollment
3. Angiographically documented >50% coronary stenosis
4. Prior septal myectomy or alcohol septal ablation
5. Prior myocardial infarction
6. Incessant ventricular arrhythmias
7. Diabetes with end organ damage
8. Stage IV/V chronic kidney disease (eGFR <30ml/min)
9. Inability to tolerate MRI scanning (severe claustrophobia, inability to lie flat)
10. Contraindications to CMR imaging (implantable devices or other metal implants, cranial aneurysm clips, metallic ocular foreign bodies, hypersensitivity to gadolinium)
11. Female participant who is pregnant or lactating
12. Malignancy or other serious medical condition expected to limit lifespan <5 years
13. Any other significant disease or disorder which, in the opinion of the investigator, might influence the participants ability to participate in the study.
14. Involvement in other studies thought to compromise resulting study data or the health of the participant.
15. Inability to give informed consent.

Date of first enrolment
30/06/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

United States of America

Study participating centre
Suite 300, 79 TW Alexandar Drive 4401 Research Commons
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Sponsor information

Organisation

University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH); Grant Codes: 1U01HL117006-01A1

Alternative Name(s)
US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/08/2015	10/04/2019	Yes	No
HRA research summary			28/06/2023	No	No