

Cardiopulmonary Assessment at Rest and during Exercise in patients with Sickle Cell Disease

Submission date 02/01/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/02/2018	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

People with sickle cell disease (SCD) were unlikely to survive childhood in the past but treatment has improved. There are new challenges. It is known that ageing groups of SCD patients in the UK will have complications such as raised pressure in the lungs (pulmonary hypertension) and the same will happen in developing countries. Early intensive treatment of SCD (involving exchange transfusion and drugs designed to increase haemoglobin levels, such as 5-HU) may prevent such complications. The aim of the study is to assess this, by using exercise magnetic resonance imaging and echocardiography in patients undergoing intensive conventional therapy for SCD.

Who can participate?

All adults 18 years of age and older with homozygous SCD.

What does the study involve?

The study will include 3 visits over 12 months. Each visit is expected to last no more than 60 minutes.

Visit 1: patients will be asked to do a symptom limited exercise which will normally last no more than 10 minutes. They will have the following tests: cardiac magnetic resonance scan with exercise (cMR augmented CPEX), exercise echocardiography (ECHO) and Chester Step test with respiratory gas analysis (CPEX).

Visit 2 (after 6 months): ECHO and CPEX

Visit 3 (after 12 months): all tests

The data acquired at rest and during the exercise will be compared at each visit and across the duration of study.

What are the possible benefits and risks of participating?

This study will help the understanding of the effects of sickle cell disease on the heart and lungs of patients with this condition. Magnetic resonance and echocardiography have no proven side effect (no ionising radiation).

Where is the study run from?

This study is run from the University College London Hospital (UCLH), UK.

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

Recruitment starts on 13th January 2014 and is expected to run for 1 year.

Who is funding the study?

Biomedical Research Centre (BRC) Cardiometabolic programme (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Prospective longitudinal clinical observational study in patients with homozygous sickle cell disease (SCD) to assess if conventional therapy alters cardiopulmonary complications

Acronym

CARE-SCD

Study objectives

Intensive conventional therapy can prevent the development of cardiopulmonary complications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West London & Gene Therapy Advisory Committee (GTAC) Health Research Authority, ref: 13/LO/1893

Study design

Prospective longitudinal clinical observational study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Sickle cell disease

Interventions

Conventional therapy including hydroxyurea and exchange transfusion. This includes the use of 5-hydroxyurea or exchange transfusions as prescribed by haematology team caring for the patient. This is standard care for sickle cell patients. Patients will be followed up under haematology routinely but have cardiac scans at baseline, 6 months and 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Cardiac Magnetic Imaging can be used to assess pulmonary vascular parameters in SCD patients
2. The pulmonary vascular responses to exercise are abnormal in patients with SCD

Timepoints of measurements: 0 months (baseline) and 12 months (end)

Key secondary outcome(s)

Treatment of SCD with transfusion therapy and 5-hydroxyurea, designed to reduce the proportion of sickle red cells, alter vascular responses to exercise

Timepoints of measurements: 0 months (baseline), 6 months (mid) and 12 months (end)

Completion date

18/01/2016

Eligibility

Key inclusion criteria

1. Patients with a diagnosis of homozygous sickle cell disease
2. Aged 18 and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Age outside inclusion criteria
2. Impaired left ventricle (LV) function
3. Valvular abnormalities
4. Sickle cell crisis within 2 weeks of recruitment.
5. Acute chest syndrome within 4 weeks of recruitment
6. Principal exclusion criteria to perform an MR scan:
 - 6.1. Permanent pacemaker
 - 6.2. Intracerebral aneurysm clip
 - 6.3. Pregnancy
7. Physical disabilities which don't permit the patient to ride on a bike
8. Principal exclusion criteria to perform a cardiopulmonary exercise test:
 - 8.1. Myocardial infarction (35 days)
 - 8.2. Syncope
 - 8.3. Uncontrolled heart failure
 - 8.4. Uncontrolled Asthma
 - 8.5. Respiratory failure
 - 8.6. Resting saturations <85%
 - 8.7. Uncontrolled arrhythmias
 - 8.8. Active endocarditis, myocarditis, pericarditis

Date of first enrolment

13/01/2014

Date of final enrolment

13/01/2015

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre
The Hatter Cardiovascular Institute
London
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Sponsor information

Organisation
University College London (UK)

ROR
<https://ror.org/02jx3x895>

Funder(s)

Funder type
Research organisation

Funder Name
Biomedical Research Centre (BRC) (UK), Ref: BRC72/CM/MW5982

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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