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

Submission date
02/01/2014

Recruitment status
No longer recruiting

Registration date
22/01/2014

Overall study status
Completed

Last Edited
02/02/2018

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Dr Emmanuel Ako; emmanuel.akoh@uclh.nhs.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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)

Secondary outcome measures
Treatment of SCD with transfusion therapy and 5-hydoxyurea, 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)

Overall study start date
13/01/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 patients with homozygous sickle cell disease

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 diabilities 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 arrythmias
8.8. Active endocarditis, myocarditis, pericarditis

Date of first enrolment
13/01/2014

Date of final enrolment
13/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Hatter Cardiovascular Institute
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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