

Prevention Of Morbidity In Sickle cell disease pilot phase

Submission date 19/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/09/2019	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.stroke.org.uk/research/funded_research/research_projects_programme_grants/research_region/london/preventing.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00415727

Secondary identifying numbers

99-NR-31

Study information

Scientific Title

Prevention Of Morbidity In Sickle cell disease pilot phase

Acronym

POMS

Study objectives

In sickle cell anaemia, nocturnal oxyhaemoglobin desaturation is associated with low processing speed index, and this morbidity can be reduced with overnight auto Continuous Positive Airways Pressure (CPAP) and/or oxygen supplementation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

St Marys Hospital Research Ethics Committee has approved the pilot phase of this study on the 25th September 2006 (ref: 06/Q0403/133).

Study design

Randomised single blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Sickle cell anaemia

Interventions

Overnight auto Continuous Positive Airways Pressure (CPAP) with oxygen supplementation if mean overnight oxyhaemoglobin saturation is not more than 94% after two weeks of autoCPAP versus no treatment.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Change in processing speed index.

Secondary outcome measures

1. Frequency of pain measured via SMS and pain diary
2. Adverse events e.g. headache, anorexia, weight loss, nausea, vomiting, reduction in steady state red or white cell count
3. Change in blood pressure
4. Number of omissions on Conners Continuous Performance Test
5. Change in Chervin sleep questionnaire
6. Change in Behaviour Rating Inventory of Executive Function (BRIEF)
7. Change in number of abnormalities (Adam's criteria) on Trans Cranial Doppler (TCD)

Overall study start date

01/11/2006

Completion date

31/10/2007

Eligibility**Key inclusion criteria**

1. Age more than four years old
2. Informed consent with assent in accordance with UK ethical committee (Central Office for Research Ethics Committees [COREC]) system must be signed by the patient's parent or legally authorised guardian acknowledging written consent to join the study. When suitable, patients will be requested to give their assent to join the study
3. Haemoglobin SS (homozygous sickle cell anaemia) diagnosed by standard techniques. Participating institutions must submit documentation of the diagnostic haemoglobin analysis

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

22

Key exclusion criteria

1. Existing respiratory failure
2. Decompensated cardiac failure
3. History of severe epistaxis
4. Trans-sphenoidal surgery, or trauma that could have left a cranio-nasopharyngeal fistula

5. Perforated ear drum
6. Bullous lung disease
7. Bypassed upper airway
8. Pneumothorax
9. Pathologically low blood pressure
10. Cerebral Spinal Fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus
11. Patients on chronic regular blood transfusion
12. Patient who received treatment with anti-sickling drugs or hydroxyurea within three months
13. Patient with other neurological problems, such as neurofibromatosis, lead poisoning, or tuberous sclerosis
14. Pregnancy
15. Sinus or middle ear infection (temporary)

Date of first enrolment

01/11/2006

Date of final enrolment

31/10/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Neuroscience Unit**

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

Institute of Child Health (UK)

Sponsor details

c/o Ms Emma Pendleton

Director of Research and Development

30 Guilford Street

London

England

United Kingdom

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Sponsor type

University/education

Website

<http://www.ich.ucl.ac.uk/ich/>

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Stroke Association (PROG 4) (UK)

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?
Results article	results	01/07/2009		Yes	No