

Prevention Of Morbidity In Sickle cell disease pilot phase

Submission date 19/11/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/01/2007	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 10/09/2019	Condition category Haematological Disorders	☐ Individual participant data

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)
NCT00415727

Protocol serial number
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).

Primary study design

Interventional

Study design

Randomised single blind trial

Study type(s)

Treatment

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(s)

Change in processing speed index.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Neuroscience Unit

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

Institute of Child Health (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Stroke Association (PROG 4) (UK)

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?
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Results article	results	01/07/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes