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Prevention Of Morbidity In Sickle cell disease pilot phase

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

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
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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