ISRCTN34508212 https://doi.org/10.1186/ISRCTN34508212

Mild induced hypothermia for severe falciparum malaria

Submission date
19/06/2013

Recruitment status
No longer recruiting

Registration date
23/10/2013

Overall study status
Completed

Last Edited
06/08/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Mild hypothermia (when body temperature drops below 35°C) has been shown to be protective in many situations in intensive care and this study aims to find out whether it could help patients with severe and cerebral malaria. This is a pilot (small scale) study.

Who can participate?
Patients admitted to intensive care with severe malaria

What does the study involve?
All patients are cooled to between 32 and 34°C using a cooled salt solution injected through their veins, in addition to standard treatment.

What are the possible benefits and risks of participating?
This technique may reduce death or brain damage from severe malaria

Where is the study run from?
This study is run from University College Hospital, London, UK and Chittagong Medical College, Chittagong, Bangladesh

When is the study starting and how long is it expected to run for?
May 2014 to May 2015

Who is funding the study?
Oxford University (UK)

Who is the main contact?
Dr Brian Angus
brian.angus@ndm.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name
Dr Brian Angus

Contact details
Rm7400, L7 The John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU
-
brian.angus@ndm.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1.3

Study information

Scientific Title
A pilot study of mild induced hypothermia for severe falciparum malaria

Study objectives
Mild induced hypothermia is safe and efficacious in severe falciparum malaria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Oxford Tropical Research Ethics Committee (OxTREC) 06-12

Study design
Non-randomised pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Malaria

Interventions
All patients will receive mild induced hypothermia along with the standard treatment. Patients will be cooled using cold intravenous saline and external cooling blankets. Patients will be followed up until discharge from the hospital.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. In-hospital mortality
2. 30 day mortality
3. Neurological outcome at day 30
4. Safety
Primary endpoints will be mortality and neurological state at baseline and discharge from hospital

Secondary outcome measures
1. Parasite clearance time
2. Clinical and biochemical measures (see below).
3. Biochemical and hemodynamic measures at the start and completion of therapy will also be compared
4. Area under the curve for microvascular reactivity by reactive hyperemia-peripheral artery tonometry (RH-PAT) [0-25 hrs]
5. Endothelial function [nearinfrared reflectance spectroscopy (NIRS) and RH-PAT]
6. Lactate clearance
7. Improvement in microvascular obstruction [Orthogonal Polarization Spectral (OPS) imaging]
8. Change in tissue oxygen consumption (measured by NIRS occlusion phase)
9. Change in NO production
10. Change in red cell deformability
11. Changes in CSF markers of neuronal and axonal damage and astroglial activation

Overall study start date
01/05/2014

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Age 16-60 years
2. Informed consent obtained (plus parental/guardian assent if 16 or 17 years old)
3. Time of commencement of artesunate ≤18 hrs before therapy
4. Any level of Plasmodium falciparum parasitemia, and one or more of the following criteria:
4.1. Acute renal failure (creatinine >265umol/L)
4.2. Hyperbilirubinemia (total bilirubin >50 umol/L) with either renal impairment (creatinine >130umol/L) or parasitemia of >100,000 parasites/uL
4.3. Blackwater fever
4.4. Hyperparasitemia (>10% parasitised red cells)
4.5. Cerebral malaria (Glasgow coma score <11)
4.6. Hypoglycemia
4.7. Respiratory distress (RR >32)
4.8. Venous bicarbonate 12-15 meq/L (pilot phase) or 8-15 meq/L

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Pregnancy or lactation
2. Diabetes
3. Serious pre-existing disease (cardiac, hepatic, kidney)
4. History of contraindications to hypothermia (Raynauds disease, Cryoglobulinemia, Sickle Cell disease, serum cold agglutinins, Buergers disease)
5. Bleeding disorders (e.g., hemophilia)
6. An intranasal obstruction or known skull base fracture

Date of first enrolment
01/05/2014

Date of final enrolment
01/05/2015

Locations

Countries of recruitment

Bangladesh

England

United Kingdom

Study participating centre
The John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Centre for Tropical Medicine
Churchill Hospital
Headington
Oxford
England
United Kingdom
OX9 9LJ
-
paul.hogben@ndm.ox.ac.uk

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
University of Oxford (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