

Mild induced hypothermia for severe falciparum malaria

Submission date 19/06/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/10/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/08/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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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 $>265\mu\text{mol/L}$)
 - 4.2. Hyperbilirubinemia (total bilirubin $>50\mu\text{mol/L}$) with either renal impairment (creatinine $>130\mu\text{mol/L}$) 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, Buerger's 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
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Sponsor information

Organisation
University of Oxford (UK)

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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