

Saving Brains: the Artesunate Suppository Severe Malaria Cohort

Submission date 21/03/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/05/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 25/01/2019	Condition category Infections and Infestations	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Malaria kills, but because it affects the central nervous system (CNS) it also causes disability. Reliable data on malaria-caused disability risk does not exist and could help prevent the burden in the future. Our research will trace children who were part of a severe malaria study between 2000-2006 in three countries in Africa and Asia (Study 13) carried out by Chittagong Medical College-Bangladesh, National Institute of Medical Research-Tanzania and Navrongo Health Research Centre- Ghana.

Who can participate?

The parents and the original cohort of children (part of study 13), who are now at an age (8-16) at which they can be assessed for functional disability will be invited to participate in the study. It will be explained that if they participate they will undergo clinical and brain function (neurocognitive) tests. The original investigators from Study 13 will be involved, supported by psychologists, trained assessors and paediatric neurologists.

What does the study involve?

The research will follow up the original cohort of children and assess them through clinical and neurocognitive tests to establish how many of the original cohort of children is normal for their age and how many have mild, moderate or gross functional impairment. It will try to determine whether the degree of functional disability is related to their history of severe or cerebral malaria and whether effective treatment given early during the episode protected the child from disability. No intervention / treatment is given in this study.

What are the possible benefits and risks of participating?

Some children may benefit from a clinical examination, and those with disabilities will be referred for care. There are no direct risks in participating.

Where is the study run from?

Bangladesh, Ghana, Tanzania

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

The study will run for approximately 24 months. First there will be preparatory development of

the assessment tests and training of assessors. This should be completed by spring-2013 in Bangladesh, and pilot tested in a non-study cohort of children. Thereafter the training of assessors and pilot tests will occur in Tanzania and Ghana. Assessments of children from the study cohort will likely begin after mid-2013 and will take at least one year.

Who is funding the study?

The study funded by Grand Challenges Canada.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

Study13 Follow up

Study information

Scientific Title

Long-term neurocognitive assessment of children following an episode of severe malaria: the artesunate suppository trial cohort

Acronym

SBASSMC

Study objectives

To describe the long-term effects of cerebral malaria or other central nervous system (CNS) infection in childhood on the prevalence of neurological deficit in a cohort re-visited 7-13 years later.

Children with history and no history of CNS malaria will be assessed clinically, psychologically and with neuro-physiological assessments.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ghana Navrongo Health Research Centre - Ethics approval was on 30 January 2013 ref NHRCIRB148
2. Tanzania National Institute of Medical Research Ethics approval was on 4th December 2012
3. Bangladesh Chittagong Medical College approval was on 13.10.2012
4. Oxford-OXTREC approval was on 22 October 2012: Reference 169-12

Primary study design

Observational

Study design

Cohort study

Study type(s)

Other

Health condition(s) or problem(s) studied

Cerebral malaria or other CNS infection

Interventions

This is a follow up study to assess the effects of malaria on brain function. No intervention is anticipated.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To describe the long-term effects of cerebral malaria or other CNS infection in childhood on the prevalence of neurological deficit in a cohort re-visited 7-13 years later

Key secondary outcome(s)

Prevalence of neurocognitive disability

1. To compare prevalence of neurological and cognitive deficits by detailed neurocognitive exams, by status at recruitment (2000-06)
2. To compare prevalence of neurological and cognitive deficits by detailed neurocognitive exams, by treatment allocation at recruitment and, where possible, by time to reach a health facility (2000-06)
3. To compare prevalence of neurological and cognitive deficits by detailed neurocognitive

exam, by status at follow-up (2013-14)

4. To quantify types of disability by each separate neurocognitive test

Characterising neurological disability

1. To confirm and characterise the type of neurological damage by electro-encephalogram (EEG)

2. To confirm and characterise neurological damage by magnetic resonance imaging (MRI)

Development of screening tools

1. Develop and validate core metrics and neuro-development and cognitive instruments to measure neurocognitive disability in participating sites

2. Map using GPS all study participants houses

Completion date

01/03/2017

Eligibility

Key inclusion criteria

TQQ+ questionnaire, socioeconomic status, clinical history, height on:

1. Surviving children originally enrolled in Study 13

2. Male or female

3. Written informed consent by legally acceptable representative (plus assent if appropriate)

4. Willingness and ability of the participants/guardians to comply with the study tests

Detailed neurocognitive exams

1. ~30% stratified sample of the surviving study cohort meeting criteria above

2. TQQ positive children

3. >8 years of age

(Additional inclusion criteria will apply for participants who undergo EEG and/or MRI)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

TQQ+

1. Signs of acute illness

Detailed neurocognitive exams

1. Signs of acute illness

2. Anti-malarial injection at enrolment into Study 13

(Additional exclusion criteria will apply for participants who will undergo EEG and/or MRI)

Date of first enrolment

15/04/2013

Date of final enrolment

31/08/2014

Locations

Countries of recruitment

Bangladesh

Ghana

Tanzania

Thailand

Study participating centre

Mahidol Oxford Research Unit

Bangkok

Thailand

10400

Sponsor information

Organisation

Mahidol Oxford Tropical Medicine Research Unit (MORU) (Thailand)

ROR

<https://ror.org/03fs9z545>

Funder(s)

Funder type

Government

Funder Name

Grand Challenges Canada

Alternative Name(s)

Grands Défis Canada, gchallenges, Grand Challenges Canada / Grands Défis Canada, grandchallengescanada, GCC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as informed consent for the purpose was not sought. Participants were explicitly informed that their individual data would only be made available to investigators who were part of the study. Should a later follow-up occur, and informed consent be obtained, this situation may change.

IPD sharing plan summary

Not expected to be made available