

# Saving Brains: the Artesunate Suppository Severe Malaria Cohort

<b>Submission date</b> 21/03/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/01/2019	<b>Condition category</b> 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

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?

Prof Abul Faiz  
Mahidol Oxford Research Unit  
Faculty of Tropical Medicine  
Mahidol University  
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Bangkok  
10400  
Thailand

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Abul Faiz

**Contact details**

Mahidol Oxford Research Unit  
Faculty of Tropical Medicine  
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420/6 Rajvithi Rd  
Bangkok  
Thailand  
10400

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Study design**

Cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Not specified

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

15/04/2013

## **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

**Age group**

Child

**Sex**

Both

**Target number of participants**

Surviving children. ~6000

**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)

**Sponsor details**

Mahidol University Research Unit  
Faculty of Tropical Medicine  
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**Sponsor type**

University/education

**Website**

<http://www.tropmedres.ac/>

**ROR**

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

**Funder(s)****Funder type**

Government

**Funder Name**

Grand Challenges Canada

**Alternative Name(s)**

Grands Défis Canada, GCC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

30/06/2019

**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