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Saving Brains: the Artesunate Suppository Severe Malaria Cohort

Submission date
21/03/2013

Recruitment status
No longer recruiting

Registration date
28/05/2013

Overall study status
Completed

Last Edited
25/01/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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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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
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10400

Sponsor information

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

Sponsor details
Mahidol University Research Unit
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10400

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