

Rehabilitation for cognitive deficits after central nervous system malaria in Ugandan children

Submission date
10/04/2008

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
03/07/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
28/02/2019

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00658450

Protocol serial number

2006/HD11/4748U

Study information

Scientific Title

A randomised trial to investigate the effect of a rehabilitation program for cognitive deficits in Ugandan children after central nervous system malaria

Study objectives

Current hypothesis as of 05/02/2009:

Malaria with central nervous system (CNS) involvement affects several children in sub-Saharan Africa leaving some survivors with cognitive problems especially in attention and memory. There are currently no tested interventions for such deficits resulting from infectious diseases like malaria or other causes. Providing such interventions will go a long way in helping these children achieve their full potential.

The purpose of this study is to determine whether computerised cognitive rehabilitation training improves cognition in children who have had CNS malaria.

Initial hypothesis at time of registration:

Children receiving cognitive rehabilitation will have better cognitive outcomes than those not receiving cognitive rehabilitation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Makerere University Faculty of Medicine Research and Ethics Committee on the 31st October 2007
2. Uganda National Council of Science and Technology on the 11th December 2007

In addition to the proposal being reviewed on the above two dates, another approval for the new changes was given on the 14th Nov 2008.

Primary study design

Interventional

Study design

Randomised controlled single centre trial (multicentre as of 05/02/2009)

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria with CNS involvement

Interventions

A computerised cognitive training package (named Captain's Log) will be the main intervention. Children assigned to the intervention will be given cognitive training for 45 minutes, twice a week for 8 weeks (16 sessions in all). The hope is that continued use of certain cognitive functions during the training will strengthen them leading to improvement in these areas.

Duration of the treatment in the intervention arm is 16 sessions each lasting 45 minutes bi-weekly for 8 weeks (2 months). This intervention will start at 3 months post-discharge.

The control group will receive the standard post-discharge care for cerebral malaria at Mulago Hospital, the study site (treatment as usual). This includes follow up visits at the Paediatric neurology clinic if child had neurological complications at discharge. No cognitive rehabilitation takes place at this clinic.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Attention measured by the Test of Variables of Attention (TOVA).

Primary and secondary outcomes will be measured at 3 months post-discharge (just before intervention starts) and at 6 months post-discharge (a month after intervention).

Key secondary outcome(s)

Amended as of 20/10/2010:

1. Memory, visual spatial ability, learning and reasoning measured by the Kaufmann Assessment Battery for children second edition
2. Parental rating of behaviour measured by the child behaviour checklist
3. Academic functioning measured by the wide range achievement test, third edition

Primary and secondary outcomes will be measured at 3 months post-discharge (just before intervention starts) and at 6 months post-discharge (a month after intervention).

Initial information at time of registration:

1. Memory, planning and reasoning measured by the Kaufmann Assessment Battery for children second edition
2. Parental rating of behaviour measured by the child behaviour checklist
3. Academic functioning measured by the wide range achievement test, third edition

Primary and secondary outcomes will be measured at 3 months post-discharge (just before intervention starts) and at 6 months post-discharge (a month after intervention).

Completion date

01/10/2010

Eligibility**Key inclusion criteria**

Current information as of 05/02/2009:

Study will recruit children with central nervous system malaria (CNS) and healthy controls (HC).

Inclusion criteria for CNS group:

1. Aged five to 15 years, either sex
2. Presenting with asexual forms of *P. falciparum* malaria on a peripheral blood smear
3. Unarousable coma (not able to localise a painful stimulus) and no other cause for coma

(normal cerebrospinal fluid [CSF])

4. A history of seizures for the present illness

5. Impaired consciousness

Inclusion criteria for HC group:

1. Aged five to 15 years, either sex

2. No other illness at present

3. Within two years of the CNS child (for CNS children aged 5 and 6 years, the HC's age won't go below 5 and for CNS children aged 14 and 15, the HC's age won't go above 15 years)

Initial information at the time of registration:

Study will recruit children with cerebral malaria (CM) and healthy controls (HC).

Inclusion criteria for CM group:

1. Aged five to 15 years, either sex

2. Presenting with asexual forms of *P. falciparum* malaria on a peripheral blood smear

3. Unarousable coma (not able to localise a painful stimulus) and no other cause for coma (normal cerebrospinal fluid [CSF])

Inclusion criteria for HC group:

1. Aged five to 15 years, either sex

2. No other illness at present

3. Within two years of the CM child (for CM children aged 5 and 6 years, the HCs age won't go below 5 and for CM children aged 14 and 15, the HCs age won't go above 15 years)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 Years

Upper age limit

15 Years

Sex

All

Key exclusion criteria

Amended as of 20/10/2010:

Please note that the exclusion of HIV children has been removed as of 20/10/2010, meaning that children infected with HIV will now be allowed to participate in this trial.

Initial information at time of registration:

Exclusion criteria for CNS* group:

1. History of or present meningitis, encephalitis, prior CNS*, sickle cell disease (SCD), human

immunodeficiency virus (HIV) infection, epilepsy, multiple seizures

2. Developmental delay

3. History of hospitalisation for malnutrition

Exclusion criteria for HC group:

1. History of or present bacterial meningitis, encephalitis, CNS, SCD, HIV infection

2. History of hospitalisation for malnutrition

3. Any chronic illness for which the patient is currently taking medication

* Please note that this changed from CM to CNS on 05/02/09 in response to updates from the Principal Investigator)

Date of first enrolment

01/02/2008

Date of final enrolment

01/10/2010

Locations

Countries of recruitment

Uganda

Study participating centre

Makerere University Medical School

Kampala

Uganda

7072

Sponsor information

Organisation

Swedish International Development Cooperation Agency (SIDA) (Sweden)

ROR

<https://ror.org/01fn7me06>

Funder(s)

Funder type

Government

Funder Name

Department for Research Cooperation (SAREC) of the Swedish International Development Cooperation Agency (SIDA) (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/08/2011	28/02/2019	Yes	No