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Effect of S. mansoni infection on immune responses to measles immunization

Submission date
02/05/2013

Recruitment status
No longer recruiting

Registration date
26/07/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Infection with the blood fluke Schistosoma mansoni that causes schistosomiasis (also called bilharzia) is still a problem in communities along the lake shores and rivers in Uganda. Infection with S. mansoni has a very great effect on the body immunity. We think that when children are infected with S. mansoni they may respond poorly to the childhood immunizations such as measles booster immunization. We want to find out if the children among the fishing communities have good body defences against measles. We also want to find out how S. mansoni infection among children under five years and its treatment may affect the bodys defeneces against measles. With the results, we may be able to develop better ways of fighting bilharzia, measles and possibly other diseases.

Who can participate?
Children aged 3-5 years old on the Entebbe peninsula of Lake Victoria and adjacent islands of Wakiso district (Uganda).

What does the study involve?
All S. mansoni infected participants will be treated with single dose of praziquantel and children will be given measles booster immunization . S. mansoni infected children will be randomly allocated to one of the three groups (A,B and C) to receive praziquantel treatment at different times. The children will either receive praziquantel treatment two weeks before measles booster immunization (group A) or receive praziquantel and measles booster immunization on the same day (group B) or receive praziquantel one week after immunization (group C). Uninfected children who will participate in the study will only receive measles booster immunization.

What are the possible benefits and risks of participating?
Participating children will be tested for worm infections, in particular bilharzia, and are expected to benefit from the treatment for the worm infections. Participating children will get measles booster immunization. Praziquantel treatment may have some side effects like itching, rashes, dizziness and diarrhea, especially in individuals with heavy infections, but these effects are limited and the team will provide treatment for these side effects.

Where is the study run from?
The study is based at the Uganda Virus Research Institute and is conducted in collaboration with the Vector Control Division of the Ugandan Ministry of Health.

When is the study starting and for how long is it expected to run?
The study started in March 2013 and is expected to run for three years.

Who is funding the study?
European Foundations Initiative for African Research into NTDs (EFINTD)- The Fondazione Cariplo (Italy), Fundação Calouste Gulbenkian (Portugal), Fondation Mérieux (France), Nuffield Foundation (UK) and the Volkswagen Stiftung (Germany).

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
HS1307

Study information

Scientific Title
Immune Modulation and Childhood Immunization (IMoChI) Study: Immune modulation in Schistosoma mansoni infection and effects on immune responses to childhood measles immunization

Acronym

IMoChI

Study objectives
Considering that Schistosoma mansoni infection is associated with induction of strong Th2 and immune modulation profiles that could influence immune responses to non-schistosome antigens, this study aims to explore and elucidate the effect of S. mansoni infection and its treatment on the efficacy of childhood measles immunization. We will examine the hypothesis that S. mansoni infection skews measles specific immune responses towards type two responses away from the more protective type one responses. If such an effect exists it may be correlated to the magnitude of schistosome-specific type two and regulatory responses. If this is the case, concurrent de-worming and immunization may actually worsen the situation, increasing the bias to type two rather than type one responses to measles vaccination, since praziquantel treatment results in significant boost of type two immune responses. Alternatively, the removal of the immune-suppressive effects of active worm infection may result an immediate benefit for the response to measles immunization.

Thus the study will generally address the hypothesis that vaccine immunogenicity is impaired in S mansoni infected communities compared to uninfected communities in Uganda and will seek to understand the mechanisms by which S. mansoni infection exerts such effects with the following specific objectives:
1. To determine the effects of S. mansoni infection on antibody and cellular responses to measles booster immunization in children aged three to five years
2. To determine the effects of praziquantel treatment of S. mansoni infection on antibody and cellular responses to measles booster immunization in children aged three to five years
3. To correlate immune responses to measles immunization to schistosome-specific immune responses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Uganda Virus research institute, Entebbe, 20 November 2012
The Uganda National Council for Science and Technology, Kampala 11 January 2013

Study design
Randomized intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Helminth infections and effects on childhood immunization

Interventions
All S. mansoni infected participants will be treated with single dose of praziquantel at the recommended dosage of 40mg per Kg body weight and children will be given measles booster immunization (in accordance to the Uganda Ministry of Health). S. mansoni infected children will be randomly assigned into three groups (A,B and C) to receive praziquantel treatment at different time points with respect to measles booster immunization as follows:
The children will either receive praziquantel treatment two weeks before measles booster immunization (group A) or receive praziquantel and measles booster immunization on same day (group B) or receive praziquantel one week after immunization (group C). Uninfected children who will participate in the study will only receive measles booster immunization.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
praziquantel

Primary outcome measure
Immune responses to Measles: Antibody responses and Cytokine responses will be measured at baseline, one week after measles booster immunization and 24 weeks after measles booster immunization.

Secondary outcome measures
S. mansoni infection intensity and response to praziquantel treatment will be measured at baseline and at 24 weeks after measles booster immunization.

Overall study start date
28/02/2013

Completion date
28/02/2016

Eligibility

Key inclusion criteria
Children of age 3-5 years residing on the Entebbe Peninsula in Lake Victoria and adjacent islands of Wakiso district

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
5 Years

Sex
Both

Target number of participants
225 children with S. mansoni and 50 children without S mansoni infection.

Total final enrolment
254

Key exclusion criteria
1. Children whose parents or guardian do not consent to join the study
2. Cildren who do not meet the inclusion criteria

Date of first enrolment
28/02/2013

Date of final enrolment
28/02/2016

Locations

Countries of recruitment
Uganda

Study participating centre
Uganda Virus Research Institute
Kampala
Uganda
256

Sponsor information

Organisation
The Uganda Virus Research Institute (Uganda)

Sponsor details

Plot 51-59, Nakiwogo Road
P. O. Box 49, Entebbe
Kampala
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256

Sponsor type
Research organisation

ROR
https://ror.org/04509n826

Funder(s)

Funder type
Charity

Funder Name
European Foundations Initiative for African Research into NTDsEFINTD- The Fondazione Cariplo (Italy)

Funder Name
Fundação Calouste Gulbenkian (Portugal)

Funder Name
Fondation Mérieux (France)

Funder Name
Nuffield Foundation (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
The Volkswagen Stiftung (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/02/2019		Yes	No