

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

Submission date 02/05/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/07/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Infections and Infestations	<input type="checkbox"/> 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 body's defences 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?

Dr Robert Tweyongyere; tmrobert966@gmail.com

Dr Swaibu Lule; swaiblule@gmail.com or swaiblule@yahoo.com

Contact information

Type(s)

Scientific

Contact name

Dr Robert Tweyongyere

Contact details

Uganda Virus Research Institute
P. O. Box 49, Entebbe
Kampala
Uganda
256

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomized intervention study

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Years

Upper age limit

5 Years

Sex

All

Total final enrolment

254

Key exclusion criteria

1. Children whose parents or guardian do not consent to join the study
2. Children 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)

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)

NuffieldFound

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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