

Schistosomiasis/bilharziasis in preschool and school children along shores and on islands of Lake Victoria western Kenya: identifying suitable markers for monitoring the progress of bilharzia treatment

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| Submission date 10/03/2022 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 10/05/2022 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 18/03/2022 | Condition category 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

Bilharzia is an infection caused by a parasitic worm that lives in fresh water in subtropical and tropical regions. To control bilharzia, the Kenyan government and its working partners distribute bilharzia medicine to schoolchildren who are known to face a high risk of bilharzia. However, increasing reports show preschool children also face a threat of suffering from bilharzia and can benefit from such bilharzia treatment programs. The World Health Organization supports the extension of bilharzia treatment plans in preschool children. There is therefore a need to have simple tools which can be used to measure the impact of such control programs upon the disease. Eosinophil cationic protein (ECP) is increasingly being used as an indicator for infection of the large intestines. Bloody stool is also a dependable pointer for large intestine disease. The aim of this study is to find out whether ECP and blood in stool can be used as signs of large intestine disease caused by bilharzia worms before and after treatment with praziquantel (bilharzia medicine).

Who can participate?

Children enrolled in early childhood development (ECD) (PP1) and grade 4 in primary schools within Mbita Health and Demographic Surveillance System, western Kenya

What does the study involve?

At the beginning of the study, selected children will be checked for bilharzia by examining their stool and urine. Those with bilharzia will be followed for 18 months. All children with bilharzia will be given bilharzia medicine according to the Kenyan ministry of health guidelines. A second treatment will be done 6 weeks after the initial treatment. This is to increase the chances of clearing the bilharzia parasite from the body. The two-dose treatment will be repeated at 6 and 18 months after baseline in all positive cases. Additionally, examination and treatment of soil-transmitted worms together with malaria will be done. Tests for hemoglobin in finger-prick

blood and eosinophil cationic protein and blood in feces will done at baseline, 6 and 18 months. Additionally, other data such as age, height, weight, body temperature and medical data resulting from examination of stool, urine and blood samples will be collected.

What are the possible risks and benefits of participating?

If eosinophil cationic protein and blood in feces are found to be associated with bilharzia they can be used to monitor the effectiveness of bilharzia deworming programs. Children will be treated (free of charge) if they are found to be infected with bilharzia, intestinal worms or malaria. There are no risks involved when collecting stool or urine samples from children. A fingerprick blood sample will be drawn using safe needles. This might cause slight discomfort but there will be no risk.

Where is the study run from?

Mbita Health Demographic Surveillance System (Kenya)

When is the study starting and how long is it expected to run for?

May 2020 to May 2023

Who is funding the study?

European Union

Who is the main contact?

Dr Evans Chadeka

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Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TMA2019CDF-2746

Study information

Scientific Title

Intestinal schistosomiasis in preschool and school children residing along shores and on islands of Lake Victoria western Kenya: investigation of eosinophil cationic protein and fecal occult blood as potential markers for schistosomiasis induced bowel morbidity

Acronym

ECP\$FOB

Study objectives

Overall, the study aims to investigate the applicability of eosinophil cationic protein (ECP) and fecal occult blood (FOB) as proxy markers of *Schistosoma mansoni* infection-induced intestinal morbidity before and after treatment with praziquantel. The specific objectives are:

1. Determine the prevalence of *S. mansoni* infection in preschool and school-aged children using parasitological (Kato-Katz) and CCA point-of-care (POC) kits methods.
2. Compare the fecal levels of eosinophil cationic protein and fecal occult blood in children not infected and those infected with *S. mansoni*.
3. Measure the fecal levels of eosinophil cationic protein and fecal occult blood in *S. mansoni* infected children pre and post treatment with praziquantel.
4. Evaluate the potential use of eosinophil cationic protein and fecal occult blood as markers for intestinal schistosomiasis-induced bowel morbidity.
5. Compare the performance of eosinophil cationic protein and fecal occult blood as potential surrogate markers in identifying *S. mansoni* infection-induced bowel morbidity among preschool versus school children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 05/05/2021, Kenya Medical Research Institute (KEMRI) Scientific and Ethics Research Unit (SERU, PO Box 54840 00200 Off Raila Mbagathi Road, Nairobi, Kenya; +254 (0)717719477; seru@kemri.org, kemriseru18@gmail.com), ref: SERU-4174

Study design

Observational cohort follow-up study

Primary study design

Observational

Secondary study design

Epidemiological study

Study setting(s)

School

Study type(s)

Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Schistosomiasis

Interventions

At the beginning of the study, selected children will be checked for bilharzia by examining their stool and urine. Those with bilharzia will be followed for 18 months. All children with bilharzia will be given bilharzia medicine according to the Kenyan ministry of health guidelines. A second treatment will be done 6 weeks after the initial treatment. This is to increase the chances of clearing the bilharzia parasite from the body. The two-dose treatment will be repeated at 6 and 18 months after baseline in all positive cases. Additionally, examination and treatment of soil-transmitted worms together with malaria will be done. Tests for hemoglobin in finger-prick blood and eosinophil cationic protein and blood in feces will be done at baseline, 6 and 18 months. Additionally, other data such as age, height, weight, body temperature and medical data resulting from examination of stool, urine and blood samples will be collected.

Intervention Type

Other

Primary outcome measure

1. Fecal occult blood (FOB) measured by point of care (POC) chromatographic test assessed before and after praziquantel treatment at baseline, 6 months post-baseline and end-line
2. Eosinophil cationic protein (ECP) in stool measured by ELISA assessed before and after praziquantel treatment at baseline, 6 months post-baseline and end-line

Secondary outcome measures

Hemoglobin levels measured by POC Hemocue machine before and after praziquantel treatment at baseline, 6 months post-baseline and end-line

Overall study start date

01/05/2020

Completion date

30/05/2023

Eligibility

Key inclusion criteria

1. Children enrolled in ECDs (PP1) and grade 4 in primary schools within Mbita Health and Demographic Surveillance System (HDSS), western Kenya
2. They should have stayed within the study site for the last 2 years and intend to stay for at least 2 more years

Participant type(s)

Healthy volunteer

Age group

Child

Sex

Both

Target number of participants

481

Total final enrolment

528

Key exclusion criteria

Those registered with other schistosomiasis studies

Date of first enrolment

01/10/2021

Date of final enrolment

16/12/2021

Locations

Countries of recruitment

Kenya

Study participating centre

KEMRI-NUITM Mbita Research Station

Box 30

Mbita

Kenya

40305

Sponsor information

Organisation

European & Developing Countries Clinical Trials Partnership

Sponsor details

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The Hague

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Sponsor type
Charity

Website
<http://www.edctp.org>

ROR
<https://ror.org/031jv9v19>

Funder(s)

Funder type
Government

Funder Name
European Union

Results and Publications

Publication and dissemination plan

Planned publication in open peer-reviewed journal, presentations in scientific conferences and feedback meetings with local health and education authorities within the study area.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date