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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

Submission date
10/03/2022

Recruitment status
No longer recruiting

Registration date
10/05/2022

Overall study status
Completed

Last Edited
18/03/2022

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
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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Protocol serial number
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

Primary study design
Observational

Study design
Observational cohort follow-up study

Study type(s)
Screening

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 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(s)
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

Key secondary outcome(s)
Hemoglobin levels measured by POC Hemocue machine before and after praziquantel treatment at baseline, 6 months post-baseline and end-line

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

Healthy volunteers allowed
No

Age group
Child

Sex
All

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
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Sponsor information

Organisation
European & Developing Countries Clinical Trials Partnership

ROR
https://ror.org/031jv9v19

Funder(s)

Funder type
Government

Funder Name
European Union

Results and Publications

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