

Sustaining the control of intestinal schistosomiasis mansoni in Western Kenya

Submission date 17/11/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 18/11/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/10/2017	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Schistosomiasis is a chronic (long term) infection caused by parasites that live in fresh water (for example, rivers and lakes) in tropical and subtropical countries. Symptoms of the disease vary widely and can be fairly mild (fever, skin rash, coughing) or more serious (passing blood in diarrhoea or urine, vomiting blood, stomach pains, paralysis of the legs). Over 90% of cases occur in Africa. The World Health Organisation wants to treat 75% of the population at risk of schistosomiasis infection by 2020 and preventive treatment (chemotherapy) will increase massively as a result. In Kenya, where both *S. mansoni* and *S. haematobium* are endemic and many people suffer from intestinal or urogenital schistosomiasis (schistosomiasis affecting the urinary and genital organs) no large-scale preventive chemotherapy programme had been set up before the start of this study. We want to investigate which combination of annual praziquantel treatments (given in schools or in communities) and 'drug holidays' (when no treatment is given) is the most successful for the lowest cost.

Who can participate?

Schoolchildren aged 9-12 years attending one of 75 schools in western Kenya recruited for the study.

This 5-year intervention trial takes place in 75 schools in western Kenya.

What does the study involve?

In a first step, in-depth parasitological surveys are carried out in each participating school where the number of children infected with *S. mansoni* (prevalence) ranges between 10% and 24%. Prevalence is measured using Kato-Katz thick smears (a laboratory technique for looking for parasite eggs in stool samples) from 50 children aged 13-14 years per locality (or region). Each school is then randomly allocated into one of three groups. Schoolchildren attending schools in group 1 are treated with praziquantel once a year for the 5 years of the study. Schoolchildren attending schools in group 2 are treated for the first two years of the study. Children attending schools in group 3 are treated in the first year and the third year of the study. Three days of consecutive parasitological surveys are carried out before each treatment to assess any changes to the prevalence and intensity (severity of infection) of *S. mansoni* infection over time. The praziquantel is administered by trained teachers to all children aged 5-15 years.

What are the possible benefits and risks of participating?

Disease due to schistosomiasis will be reduced among children who receive treatment of praziquantel. Praziquantel is generally well tolerated, if not taken on empty stomach. Side effects are typically mild and temporary and do not require treatment. They include malaise (feeling out of sorts), headache, dizziness, abdominal discomfort (with or without nausea), high temperature and, rarely, urticarial (hives). Children will remain under medical supervision after treatment and appropriate measures will be taken if need be.

Where is the study run from?

Kenya Medical Institute for Research

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

January 2010 to December 2016

Who is funding the study?

The Bill & Melinda Gates Foundation (USA)

Who is the main contact?

Dr Diana Karanja

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Contact information

Type(s)

Public

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Protocol serial number

Sm1 4787606

Study information

Scientific Title

Comparison of school-based mass drug administration delivery strategies for control of *Schistosoma mansoni* infections in Western Kenya

Study objectives

The implementation of two rounds of preventive chemotherapy with the antischistosomal drug praziquantel to school-aged children (exclusion of children <5 years) over a 4-year period (either alternating with drug holidays in years 2 and 4, or drug holidays in years 3 and 4) will more cost-effectively sustain the control of morbidity due to *Schistosoma mansoni* infection in areas with moderate endemicity (prevalence: 10-24%) in Kenya than the implementation of four rounds of annual chemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kenya Medical Research Institute, 25/08/2010, ref: KEMRI/RES/7/3/1

Primary study design

Interventional

Study design

Randomised intervention trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schistosomiasis

Interventions

In a first step, in-depth parasitological surveys are carried out in 75 schools where the prevalence of *S. mansoni* (i.e. number of infections) amongst schoolchildren ranges between 10% and 24%. Prevalence is measured using Kato-Katz thick smears from 50 children aged 13-14 years per locality.

Each school is then randomly allocated into one of three groups. Schoolchildren attending schools in group 1 are treated with praziquantel once a year for the 5 years of the study. Schoolchildren attending schools in group 2 are treated for the first two years of the study. Children attending schools in group 3 are treated in the first year and the third year of the study. Three days of consecutive parasitological surveys are carried out before each treatment to assess any changes to the prevalence and intensity (severity of infection) of *S. mansoni* infection over time. The praziquantel is administered by trained teachers to all children aged 5-15 years.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Praziquantel

Primary outcome(s)

Identification of the most cost-effective strategy that is able to reduce *S. mansoni* infection from moderate (10-24%) to low prevalence levels (<10%). Measured by change in prevalence and

intensity of *Schistosoma mansoni* infection in cohorts of 9- to 12-year-old children over the four years of intervention.

Key secondary outcome(s)

1. Prevalence and intensity of *S. mansoni* infections in 9- to-12- year-old schoolchildren, using Kato-Katz thick smears
2. Prevalence and intensity of *S. mansoni* infections in first-year schoolchildren, using Kato-Katz thick smears
3. Control of morbidity due to *S. mansoni* (reduction of the prevalence to <10%) in the 75 schools
4. Identification of *S. mansoni* risk factors
5. Mapping and prediction of the distribution *S. mansoni* in Western Kenya

Measured by changes in force of transmission, as assessed by infection prevalence and intensity of *S. mansoni* in first-year students and adults.

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Schoolchildren, either male or female, aged 9-12 years, attending the selected schools (in each study year)
2. First-year students, either male or female, attending the selected schools (in years 1 and 5)
3. Written informed consent signed by parents or legal guardians of the schoolchildren
4. Oral assent from schoolchildren
5. At least one stool sample provided over three consecutive days from 9- to 12- years- old children each study year
6. At least one stool sample provided from first-year students in years 1 and 5

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Children not aged 9-12 years (in years 2, 3 and 4)
2. Children not aged 9-12 years or being first-year students (in years 1 and 5)
3. No written informed consent by parents or legal guardians of schoolchildren
4. No oral assent given by schoolchildren
5. No stool sample provided (for 9- to 12-year-old children in each study year; for first-year students in years 1 and 5)

Date of first enrolment

01/12/2010

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

Kenya

Study participating centre

Kenya Medical Research Institute

PO Box 1578

Kisumu

Kenya

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Sponsor information

Organisation

University of Georgia Research Foundation / SCORE

ROR

<https://ror.org/00te3t702>

Funder(s)

Funder type

Charity

Funder Name

Bill and Melinda Gates Foundation

Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/10/2017		Yes	No
Protocol article	protocol and baseline data	26/05/2016		Yes	No