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Sustaining the control of intestinal schistosomiasis mansoni in Western Kenya

Submission date
17/11/2015

Recruitment status
No longer recruiting

Registration date
18/11/2015

Overall study status
Completed

Last Edited
24/10/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
12/01/2010

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

Participant type(s)

Mixed

Age group
Mixed

Sex
Both

Target number of participants
40,000

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
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Sponsor information

Organisation
University of Georgia Research Foundation / SCORE

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Sponsor type
University/education

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, 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

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
31/03/2016

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?
Protocol article	protocol and baseline data	26/05/2016		Yes	No
Results article	results	23/10/2017		Yes	No