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Gaining and sustaining control of Schistosomiasis in Cabo Delgado, Mozambique where the starting prevalence is greater than 25%

Submission date
14/12/2015

Recruitment status
No longer recruiting

Registration date
14/12/2015

Overall study status
Completed

Last Edited
20/01/2023

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 Mozambique, 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 and first-year students in years 1 and 5 attending the selected schools.

What does the study involve?
Participating schools are randomly allocated into one of six groups.
Group 1: School-age children and adults are treated with praziquantel once a year for the 4 years of the study
Group 2: School-age children and adults are treated for the first two years of the study and only school-age children are treated for the last two years
Group 3: School-age children and adults are treated for the first two years of the study and receive no treatment in the last two years
Group 4: School-age children are treated every year
Group 5: School-age children are treated for the first two years

Group 6: School-age children are treated for the first year and the third year
Any changes in the prevalence and intensity (severity of infection) of S. haematobium infection are measured over the 4 years of the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Catholic University of Mozambique

When is the study starting and how long is it expected to run for?
November 2011 to November 2015

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
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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
N/A

Study information

Scientific Title
Gaining and sustaining control of Schistosomiasis in Cabo Delgado, Mozambique where the starting prevalence is greater than 25%: a multi-centre randomized intervention trial

Acronym
Sm2 Mozambique

Study objectives
The implementation of preventive chemotherapy with the anti-schistosomal drug praziquantel in school-aged children (exclusion of children <5 years), and in adults randomized to study arms either receiving treatment every year, or alternating with drug holidays in years 2 and 4 or drug holidays in years 3 and 4, will more cost-effectively gain the control of prevalence and morbidity due to Schistosoma haematobium infection in areas with high endemicity (prevalence: >25%) in Mozambique than the implementation of four yearly rounds of annual chemotherapy in school-aged children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ministry Of Health, National Institute of Health, National Committee of BioEthics, Ref: 235/CNBS /10

Study design
Multi-centre randomized intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neglected Tropical Diseases, Schistosomiasis

Interventions
In the first step, in-depth parasitological surveys are carried out to identify 150 schools where the prevalence of S. haematobium (i.e., number of infections) amongst schoolchildren is greater than 24%. Prevalence during this eligibility step is measured by testing urine using urine dipsticks from 50 children aged 13-14 years per locality.

Each school is then randomly allocated into one of six groups.
Group 1: School-age children and adults are treated with praziquantel once a year for the 4 years of the study
Group 2: School-age children and adults are treated for the first two years of the study and only school-age children are treated for the last two years
Group 3: School-age children and adults are treated for the first two years of the study and receive no treatment in the last two years
Group 4: School-age children are treated every year
Group 5: School-age children are treated for the first two years
Group 6: School-age children are treated for the first year and the third year

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. haematobium infection over time. The praziquantel is administered by trained teachers to all children aged 5-15 years in schools and by drug distributors in the community MDA venues.

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. haematobium infection from high prevalence levels measured by change in prevalence and intensity of Schistosoma haematobium infection in 9- to 12-year-old children over the four years of intervention.

Secondary outcome measures
1. Prevalence and intensity of S. haematobium infections in 9- to-12- year-old schoolchildren.
2. Prevalence and intensity of S. haematobium infections in first-year schoolchildren.
3. Control of morbidity due to S. haematobium (reduction of the prevalence to <10%) in the 150 schools
4. Identification of S. haematobium risk factors
5. Mapping and prediction of the distribution S. haematobium in Cabo Delgado Region, Mozambique.

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

Overall study start date
02/11/2011

Completion date
31/12/2015

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 urine sample provided over three consecutive days from 9- to 12-year-old children each study year
6. At least one urine sample provided from first-year students and adults in years 1 and 5

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
105,000

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

Date of first enrolment
02/11/2011

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
Mozambique

Study participating centre
Catholic University of Mozambique
Beira
Mozambique
960

Sponsor information

Organisation
University of Georgia Research Foundation / SCORE (USA)

Sponsor details
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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

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	15/11/2018		Yes	No
Interim results article	Protocol and baseline data for a multi-year cohort study of the effects of different mass drug treatment approaches on functional morbidities from schistosomiasis in four African countries	29/09/2017	20/01/2023	Yes	No
Other publications	Challenges in Protocol Development and Interpretation of the Schistosomiasis Consortium for Operational Research and Evaluation Intervention Studies	12/05/2020	20/01/2023	Yes	No
Other publications	Impact of Different Mass Drug Administration Strategies for Gaining and Sustaining Control of Schistosoma mansoni and Schistosoma haematobium Infection in Africa	12/05/2020	20/01/2023	Yes	No