ISRCTN32045736 https://doi.org/10.1186/ISRCTN32045736

Community-wide and School-based Mass Drug Administration (MDA), using praziquantel, given once each year compared to Community-wide and School-based Mass Drug Administration (MDA) given twice each year, six months a part, in gaining and sustaining control of Schistosoma haematobium

Submission date
14/12/2015

Recruitment status
No longer recruiting

Registration date
16/12/2015

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 long-term (chronic) infection caused by parasites that live in fresh water (for example, rivers and lakes) in tropical and subtropical countries, with over 90% of cases occurring in Africa. It can range from very mild (fever, skin rash, coughing) to more serious (passing blood in diarrhoea or urine, vomiting blood, stomach pains, paralysis of the legs). The World Health Organisation wants to treat 75% of the population who are at risk of a schistosomiasis infection by 2020 and preventive treatment (chemotherapy) will increase massively as a result. In Kenya, the main parasites which cause schistosomiasis (Schistosoma mansoni and Schistosoma haematobium) are common, and so many people suffer from schistosomiasis affecting the urinary and genital organs (intestinal or urogenital schistosomiasis). Before this study, no large-scale preventive chemotherapy programme had been set up in this area. The aim of this study is to use Mass Drug Administration (MDA) in schools and the community in Niger in order to find out the best treatment regimen for the lowest cost.

Who can participate?
First-year adult students in years 1 and 5, and school children aged between 9 and 12 who attend participating schools in Kenya.

What does the study involve?
Each school which is taking part in the study is randomly allocated to one of six groups. In the first group, school-age children and adults are treated with praziquantel once a year for the 4 years of the study. In the second group, school-age children and adults are treated once a year

for the first two years of the study and then treated twice a year in years 3 and 4. In the third group, school-age children only are treated once a year for the 4 years of the study. In the fourth group, school-age children only are treated once a year for the first two years of the study and then treated twice a year in years 3 and 4. In the fifth group, school-age children only are treated in year one, on holiday (no treatment) in year 2 of the study and receive treatment once each year in years 3 and 4. In the sixth group, school-age children only are treated once in year 1, on holiday in year 2, and receive 2 treatments every 6 months in years 3 and 4. Throughout the study period, urine samples are taken from participants in order to test for infection.

What are the possible benefits and risks of participating?
There are no risks from the collection of urine for testing for infection. If a person is infected, then they will benefit from receiving treatment. The expected benefit to the village is that the force of transmission will be reduced by the medication provided thus reducing reinfection rates and illness.

Where is the study run from?
RISEAL Niger (Niger)

When is the study starting and how long is it expected to run for?
March 2010 to June 2016

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

Who is the main contact?
Dr Amadou Garba

Contact information

Type(s)
Public

Contact name
Dr Amadou Garba

Contact details
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Additional identifiers

Study information

Scientific Title
Community-wide and school-based annual treatment compared to community-wide and school-based double treatment in controlling Schistosoma haematobium

Acronym
Sh Niger

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 twice a year will more cost-effectively gain and sustain the control of prevalence and intensity due to Schistosoma haematobium infection versus treatment once a year with treatment implemented in schools and community venues.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Advisory Committee on Ethics, 22/07/2010, ref: No.011/2014/CCNE
2. Imperial College Research Ethics Committee, 30/07/2010, ref: ICREC_8_2_2

Study design
Community and school-based randomized parallel trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schistosomiasis

Interventions
In a first step, in-depth parasitological surveys are carried out to identify 225 schools where the prevalence of S. haematobium (i.e. number of infections) amongst schoolchildren is greater than 10%.

Each school is then randomly allocated into one of six groups, who receive their praciquantel in different treatment regimens. In all groups, the praziquantel is delivered by trained teachers in schools and by drug distributors in the community MDA venues.

Group 1: School-age children and adults in this group are treated with praziquantel once a year for the 4 years of the study.
Group 2: School-age children and adults are treated once a year for the first two years of the study and then treated twice a year in years 3 and 4.
Group 3: School-age children only are treated once a year for all 4 years.
Group 4: School-age children only are treated once a year for the first two years and then twice a year in years 3 and 4.
Group 5: School-age children are treated in year one, on holiday (no treatment) in year 2 of the study and receive treatment once each year in years 3 and 4.
Group 6: School-age children receive treatment once in year 1, on holiday in year 2, and receive 2 treatments every 6 months in years 3 and 4.

Each Year the follow-up includes additional prevalence and intensity testing in the 225 schools, which includes all study Arms. This is collection of urine from each participant and testing that specimen for presence or absence of S. haematobium eggs.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Praziquantel

Primary outcome(s)
MDA strategy that is able to reduce S. haematobium infection measured by change in prevalence and intensity of Schistosoma haematobium infection in 9- to 12-year-old children is measured at baseline, 1, 2, 3 and 4 years by filtering the urine and preparing slide for microscopic exam. In addition, the urine is observed to see if hematuria visible.

Key secondary outcome(s))
1. Prevalence and intensity of S. haematobium infections in 9- to-12- year-old schoolchildren is measured at baseline, 1, 2, 3 and 4 years using urinalysis
2. Prevalence and intensity of S. haematobium infections in first-year schoolchildren is measured at baseline, 1, 2, 3 and 4 years using urinalysis
3. Identification of S. haematobium risk factors is measured by collecting village inventory data about water, sanitation, hygiene and water body contact at baseline, 1, 2, 3 and 4 years
5. Mapping and prediction of the distribution S. haematobium in Niger is measured by collecting and using GIS coordinates of schools, water bodies and water and sanitation infrastructure at baseline, 1, 2, 3 and 4 years

Completion date
30/06/2016

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 urine sample provided from 9- to 12- years- old children each study year
6. At least one urine sample provided from first-year students and adults 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. Adults in Years 2, 3 and 4
2. Children under 9 in Years 2, 3, 4
3. No written informed consent by parents or legal guardians of schoolchildren
4. No oral assent given by schoolchildren
5. 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
01/01/2012

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Niger

Study participating centre
RISEAL Niger
333 Avenue of Zarmakoye
Niamey
Niger
8000

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
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?
Results article	results	01/07/2020	11/02/2021	Yes	No
Protocol article	protocol and baseline data	26/05/2016		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