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Sustaining the control of intestinal schistosomiasis mansoni in western Côte d'Ivoire

Submission date
10/09/2014

Recruitment status
No longer recruiting

Registration date
12/11/2014

Overall study status
Completed

Last Edited
31/05/2016

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 infection caused by parasites that occurs in 78 tropical and subtropical countries. Symptoms of the disease vary widely and can be fairly mild (fever, skin rash, coughing) or more severe (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 Côte d'Ivoire, where both S. mansoni and S. haematobium are endemic and many people suffer from intestinal or urogenital schistosomiasis, 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) and 'drug holidays' (when no treatment is given) is the most successful for the lowest cost.

Who can participate?
This 5-year intervention trial takes place in 75 schools in western Côte d'Ivoire.

What does the study involve?
In a first step, in-depth parasitological surveys are carried out in 75 schools across more than 250 localities 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.

What are the possible benefits and risks of participating?
The morbidity 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?
The study is jointly run by:
1. The Université Félix Houphouët-Boigny in Abidjan (Côte d'Ivoire)
2. The Programme National de Lutte contre la Schistosomiase, les Géohelminthiases et la Filariose lymphatique (PNL-SGF) (Côte d'Ivoire)
3. The Programme National de Santé Scolaire et Universitaire (PNSSU) of the Ministry of Health and Public Hygiene in Abidjan (Côte d'Ivoire)
4. The Swiss Tropical and Public Health Institute (Swiss TPH), Basel (Switzerland)
5. Schistosomiasis Control Initiative (SCI) of Imperial College London (UK)

When is the study starting and how long is it expected to run for?
December 2011 to May 2017.

Who is funding the study?
1. The Bill & Melinda Gates Foundation through the Schistosomiasis Consortium for Operational Research and Evaluation (SCORE) based at the University of Georgia (sub-awards no. RR374-053 /4893196)
2. The Schistosomiasis Control Initiative - Imperial College (SCI; London, United Kingdom) donates praziquantel tablets

Who is the main contact?
Professor Eliézer K. N'Goran
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Study website
http://score.uga.edu/Sustaining.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Sustaining control of schistosomiasis mansoni in moderate endemicity areas in western Côte d'Ivoire

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 Côte d'Ivoire than the implementation of four rounds of annual chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Comité National d'Éthique et de la Recherche, Ministère de la Santé et de l'Hygiène Publique, 5 /5/2010, ref. 1994 MSHP/CNER
2. Ethikkommission beider Basel, 21/10/2010, ref. 279/10

Study design
Randomised intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Distribution of an information sheet to each study participant and oral explanation of the study objectives, risk and benefit (please use the contact details below to request a patient information sheet). One specific team designated to inform district and village authorities and childrens parents/guardians, with detailed information provided about the forthcoming cross-sectional parasitological and questionnaire surveys. Radio and television announcements to inform the whole population.

Health condition(s) or problem(s) studied
Schistosoma mansoni infection

Interventions
The study will be implemented in 75 schools of western Côte d'Ivoire. The 75 schools are randomly assigned to three study arms (25 schools per arm)
1. Schools of arm A: treated annually with praziquantel in years 1, 2, 3 and 4
2. Schools of arm B: treated with praziquantel in the first two years (years 1 and 2)
3. Schools of arm C: treated with praziquantel in year 1 and again in year 3

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
As of 21/03/2016:
Prevalence and intensity of S. mansoni infections in 9- to-12- year-old schoolchildren.

Initial:
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
As of 21/03/2016:
1. Prevalence and intensity of S. mansoni infections in first-year schoolchildren
2. Control of morbidity due to S. mansoni (reduction of the prevelance to <10%) in the 75 schools
3. Identification of S. mansoni risk factors
4. Mapping and prediction of the distribution S. mansoni in western Côte d'Ivoire

Initial
1. Prevalence and intensity of S. mansoni infections in 9- to-12- year-old schoolchildren
2. Prevalence and intensity of S. mansoni infections in first-year schoolchildren
3. Control of morbidity due to S. mansoni (reduction of the prevelance to <10%) in the 75 schools
4. Identification of S. mansoni risk factors
5. Mapping and prediction of the distribution S. mansoni in western Côte d'Ivoire

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
01/12/2011

Completion date
30/05/2017

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)
Patient

Age group
Child

Lower age limit
9 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
42,500

Key exclusion criteria
1. Children not attending the selected schools
2. Children not aged 9-12 years (in years 2, 3 and 4)
3. Children not aged 9-12 years or being first-year students (in years 1 and 5)
4. No written informed consent by parents or legal guardians of schoolchildren
5. No oral assent given by schoolchildren
6. No stool sample provided (for 9- to12-year-old children in each study year; for first-year students in years 1 and 5)

Date of first enrolment

01/12/2011

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
Côte d'Ivoire

Switzerland

Study participating centre
Socinstrasse 57
Basel
Switzerland
4051

Sponsor information

Organisation
Swiss Tropical and Public Health Institute (Switzerland)

Sponsor details
Socinstrasse 57
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Sponsor type
Government

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Other

Funder Name

The Bill & Melinda Gates Foundation through the Schistosomiasis Consortium for Operational Research and Evaluation (SCORE) based at the University of Georgia (sub-awards no. RR374-053 /4893196)

Funder Name
The Schistosomiasis Control Initiative - Imperial College (SCI; London, United Kingdom) donates praziquantel tablets

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/12/2014		Yes	No
Other publications	parasitological survey	03/06/2015		Yes	No
Results article	results	20/01/2016		Yes	No
Other publications	baseline findings	01/02/2016		Yes	No
Protocol article	protocol and baseline data	26/05/2016		Yes	No