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Interrupting seasonal transmission of bilharzia and control of intestinal worm infections in northern and central Côte d'Ivoire

Submission date
25/11/2016

Recruitment status
No longer recruiting

Registration date
21/12/2016

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 infection caused by a parasitic worm that lives in tropical and subtropical countries. Symptoms of the disease vary and can range from mild (fever, skin rash, coughing) to severe (passing blood in diarrhoea or urine, vomiting blood, stomach pains, paralysis of the legs). Over 90% of cases occur in Africa. People are infected during routine farming, domestic, work-related and recreational activities which expose them to infested water. Poor hygiene and certain play habits of school-aged children such as swimming or fishing in infested water make them especially vulnerable to infection. Schistosomiasis control focuses on reducing disease through periodic, large-scale population treatment (mass drug administration (MDA)) with a drug called praziquantel, which treats the infection. A more comprehensive approach including potable (safe to drink) water, adequate sanitation and snail control would also reduce transmission. The aim of this study is to find out whether MDA with praziquantel with snail control three times a year is better at preventing the spread of schistosomiasis than annual or biannual MDA alone.

Who can participate?
Children aged 5-12 years and adults aged 20-55 years who live in a participating village.

What does the study involve?
Participating villiages are randomly allocated to one of four groups. Participants living in villages in the first group receive yearly MDA of praziquantel and albendazole (another drug for treating parasitic worm infections) before the peak season for schistosomiasis (November/December) for three years. Participants living in villages in the second group receive yearly MDA of praziquantel and albendazole after the peak season of schistosomiasis (March/April) for three years. Participants living in villages in the third group receive twice yearly MDA of praziquantel and albendazole before and after peak transmission of schistosomiasis (November/December and March/April) for three years. Participants living in villages in the fourth group yearly MDA of praziquantel and albendazole as well as having chemical snail control applied to water sources three times a year for three years. At the start of the study and then after one, two and three years, participants in all gorups provide a urine sample to test for schistosomiasis infection. In

addition, at the same times, the amount of snails and infection rates are assessed in villiages in the fourth group.

What are the possible benefits and risks of participating?
Participants who receive praziquantel and who are living in areas where the intermediate host snail population is reduced may benefit from a reduction in illness due to schistosomiasis. There are no specific risks associated with this study.

Where is the study run from?
The study takes place in 60 villages in northern and central Côte d'Ivoire and is 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. The Natural History Museum (NHM), London (United Kingdom)
6. Schistosomiasis Control Initiative (SCI) of Imperial College, London (United Kingdom)

When is the study starting and how long is it expected to run for?
May 2014 to February 2019

7. 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 (USA)
2. The Schistosomiasis Control Initiative Imperial College (UK)

Who is the main contact?
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Study website
http://score.uga.edu/

Contact information

Type(s)
Scientific

Contact name
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Contact details
Swiss Tropical and Public Health Institute
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Basel
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Interrupting seasonal transmission of Schistosoma haematobium and control of soil-transmitted helminths in northern and central Côte d'Ivoire

Study objectives
In an area with a high Schistosoma haematobium transmission seasonality, annual mass drug administration (MDA) timed with tri-annual chemical snail control will better reduce schistosomiasis transmission than annual or biannual MDA.

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 Lutte contre le SIDA, 02/02/2016, ref: 007/MSLS/CNER-kp
2. Direction Générale des Productions et de la Sécurité Alimentaire, Ministère de l'Agriculture, 27 /01/2015, ref: 0163/MINAGRI/DGPSA/DPVCQ
3. Ethikkommission Nordwest- und Zentralschweiz (EKNZ, Switzerland), 15/04/2015, ref: UBE-15 /34

Study design
Four-arm cluster randomised intervention trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

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 to request a patient information sheet). One specific team designated to inform district and village authorities and children's

parents/guardians, with detailed information provided about the forthcoming cross-sectional parasitological surveys. Radio and television announcements to inform the whole population.

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

Interventions
The study will take place in 60 villages of northern and central Côte d'Ivoire. The 60 villages are randomly assigned to four study arms (15 villages per arm).

Arm A: Villages receive annual mass drug administration (MDA) with praziquantel and albendazole before the peak transmission season of schistosomiasis (November/December)
Arm B: Villages receive annual MDA with praziquantel and albendazole after the peak transmission season of schistosomiasis (March/April)
Arm C: Villages receive two yearly MDAs with praziquantel and albendazole before and after peak transmission of schistosomiasis (November/December and March/April)
Arm D: Villages receive annual MDA with praziquantel and albendazole before peak transmission of schistosomiasis (November/December), coupled with chemical snail control using niclosamide (3 applications per year; before, during and shortly after peak transmission)

In all study arms, participants complete surveys are completed among three population cohorts (i.e. up to 50 children aged 5-8 years; 100 children aged 9-12 years and 50 adults aged 20-55 years) at baseline, 1, 2 and 3 years.

Intervention Type
Mixed

Primary outcome measure
Prevalence and intensity of S. haematobium infection is assessed using the standard urine filtration method and microscopy at baseline, 1, 2 and 3 years.

Secondary outcome measures
1. Snail abundance and infection rates are assessed using malacological surveys (i.e. searching for intermediate host snails by hand and with scoops for 15 min in a defined area of a natural open freshwater body) in arm 4 only at baseline, 1, 2 and 3 years
2. Presence and number of intestinal helminth eggs will be assessed with the Kato-Katz method at baseline, 1, 2 and 3 years

Overall study start date
15/05/2014

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Children, females and males, aged 5-12 years
2. Adults, females and males, aged 20-55 years
3. Resident in one of the 60 villages in northern and central Côte d'Ivoire that are part of the

study
4. Written informed consent signed by adults (aged 20-55 years) and parents/guardian of children (aged 5-12 years) and oral assent by children
5. Able and willing to provide single urine and stool samples during the annual cross-sectional surveys
6. No known allergy to study medication (i.e. praziquantel)

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
58,000

Key exclusion criteria
1. Children not aged 5-8 years or 9-12 years
2. Adults not aged 20-55 years
3. No written informed consent by adults, and parents/guardian on behalf of their children
4. Pregnancy in female participants
5. Known allergy to study medication (i.e. praziquantel)

Date of first enrolment
01/09/2015

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
Côte d'Ivoire

England

Switzerland

United Kingdom

Study participating centre
Swiss Tropical and Public Health Institute
Socinstrasse 57
Basel
Switzerland
4051

Study participating centre
Université Félix Houphouët-Boigny
22
Abidjan
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Study participating centre
Natural History Museum
Cromwell Road
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United Kingdom
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Study participating centre
Schistosomiasis Control Initiative
Department of Infectious Disease Epidemiology
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Sponsor information

Organisation
Swiss Tropical and Public Health Institute

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Sponsor type
Research organisation

Website

http://www.swisstph.ch/

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Charity

Funder Name
The Bill & Melinda Gates Foundation through the Schistosomiasis Consortium for Operational Research and Evaluation (SCORE) based at the University of Georgia in Athens, Georgia, United States of America, funds this operational research project (sub-award no. RR374-092/S000690)

Funder Name
2. The Schistosomiasis Control Initiative (SCI) based at the Imperial College in London, United Kingdom, donates the praziquantel tablets

Results and Publications

Publication and dissemination plan
Planned publication of study protocol and the study results in the peer-reviewed (whenever possible open-access) literature before the end of 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/03/2019		Yes	No
Protocol article		29/01/2018	23/04/2021	Yes	No
Results article		08/01/2021	23/04/2021	Yes	No
Results article		06/07/2022	20/01/2023	Yes	No