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Combining treatment, sanitation and health education to control neglected tropical diseases

Submission date
19/07/2017

Recruitment status
No longer recruiting

Registration date
16/08/2017

Overall study status
Completed

Last Edited
23/04/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the developing world hundreds of millions of people suffer from intestinal parasitic worms (helminths) and intestinal protozoon infections (e.g. amoebiasis). These are often referred to neglected tropical diseases. This worm like organisms feed on their host, taking the nutrition and causing weakness and disease. More than 1 billion people are infected with soil-transmitted helminths, schistosomes and intestinal protozoa and the annual global burden might be as high as that owing to malaria or tuberculosis. This can cause undernourishment, dysentery (infection of the intestines) and diarrhea. It has been shown that parasitic infections in childhood can interfere with cognitive development (mental) and can have negative effects in adulthood. The global strategy to control helminthiasis is preventive chemotherapy, which is the regular administration of anthelminthic drugs (medication that works to treat parasitic worms) to at-risk populations. However, re-infection can occur due to unclear water and poor sanitation and hygiene behaviors. Despite evidence that water supply and sanitation are key factors for prevention and sustainable control of parasitic worms, preventive chemotherapy does not take this into account. The aim of this project is to provide an integrated and sustainable approach to control neglected diseases, by assessing the effects of a treatment program on reinfection rates and intestinal protozoa in selected villages within the Taabo health and demographic surveillance site in south-central Côte d'Ivoire and understanding the communities knowledge, attitudes, practices and beliefs about helminth and intestinal protozoon infection and communities' defecation-related.

Who can participate?
Anyone living in the Taabo health and demographic surveillance site in south-central Côte d' Ivoire who do not have a difficult health condition.

What does the study involve?
This study is conducted in eight villages. Half of the villages benefit from integrated control, whereas the other four villages are only be targeted by preventive chemotherapy. All study participants provide one urine and one stool sample and respond to a questionnaire (only the household heads) at the beginning of the study (baseline survey) and one year later (follow-up survey). Right after the baseline survey those study participants living in half of the villages (intervention villages) participate in the CLTS and health education sessions, while all study

participants will receive anthelminthic treatment once the households have built latrines. A number of quantitative studies will be carried out using questionnaires, key informant interviews (KIIs) and focus group discussions (FGDs) in order to assess participants knowledge, behaviours, attitudes and beliefs about parasitic worms and defacation.

What are the possible benefits and risks of participating?
Participants may benefit from receiving free treatment against parasitic infections. There are no anticipated risks with participating. Treatment is safe and side-effects rare and mild. The questionnaire may have some questions that might be embarrassing, discomforting or too personal; however participants can skip these questions when they decide to participate.

Where is the study run from?
This study is being run by the Centre Suisse de Recherches Scientifique en Côte d'Ivoire (Switzerland) and takes place in

When is the study starting and how long is it expected to run for?
June 2011 to December 2012

Who is funding the study?
UBS Optimus Foundation (Switzerland)

Who is the main contact?
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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
An integrated approach to control neglected tropical diseases

Acronym
N/A

Study objectives
Preventive chemotherapy combined with community-led total sanitation (CLTS) and culturally appropriate health education results in significantly lower reinfection rates with helminths and intestinal protozoa infections than preventive chemotherapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical commission of Basel (Ethikkommission beider Basel), 25/07/2011, ref: 177/11
2. National ethics and research board, CNER (Comité National d'Ethique et de la Recherche), 2011, ref: 13324 MSLS/CNER-P

Study design
Intervention cross-sectional trial

Primary study design
Interventional

Secondary study design

Study setting(s)
Community

Study type(s)
Prevention

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
Neglected tropical diseases (helminths and intestinal protozoa)

Interventions

Participants infected with schistosomes or soil-transmitted helminths received praziquantel and albendazole, respectively, after the baseline and follow-up survey. The villages for the intervention were selected if a natural leader in the community could be identified.

Praziquantel (single 40 mg/kg dose according to a dose pole for individuals aged >4 years) and albendazole (single 400 mg dose for individuals aged >2 years and single 200 mg dose for 1-2 year old children), which are safe and efficacious drugs against schistosomiasis and soil-transmitted helminthiasis, are given to the whole study population in eight communities.

While all the eight communities receive preventive chemotherapy, four communities additionally receive health education sessions and a community-led total sanitation (CLTS) intervention. Health education sessions include focus group discussions with community members about infection risk and preventive actions and the importance of building latrines for the health of the individual, household and community. CLTS is a community-participatory approach that aims to increase awareness of the sanitation profile in the community and to empower the community to take action, thus, to build latrines and stop open defecation.

Intervention Type
Mixed

Primary outcome measure
Reinfection rates with soil-transmitted helminths, schistosomes and intestinal protozoa are measured using the Kato-Katz (for soil-transmitted helminths and Schistosoma mansoni), urine filtration (for S. haematobium) and SAF methods, respectively, one year after the baseline survey.

Secondary outcome measures
Communities' defecation-related knowledge, attitude, practice and beliefs (KAPB) with regard to sanitation is measured using household questionnaires at baseline and one year.

Overall study start date
01/06/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Written informed consent by a parent/guardian on behalf of the child younger than 18 years or written informed consent by adult participant
2. Submission of 1 urine and 1 stool sample at baseline
3. Completion of questionnaire by head of household in the community survey at baseline
4. Absence of difficult health condition as assessed by a medical doctor at baseline

Participant type(s)
Mixed

Age group
All

Sex
Both

Target number of participants
4000

Key exclusion criteria
1. No written informed consent or no parental/legal guardian’s permission to participate.
2. No complete set of urine and stool sample submitted at baseline
3. No completion of questionnaire by head of household in the community survey at baseline
4. Too sick to participate in the study (e.g. high fever, severe anaemia, severe diarrhoea, etc.)

Date of first enrolment
15/07/2011

Date of final enrolment
15/09/2012

Locations

Countries of recruitment
Côte d'Ivoire

Study participating centre
Centre Suisse de Recherches Scientifique en Côte d'Ivoire
Côte d'Ivoire
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Sponsor information

Organisation
Centre Suisse de Recherches Scientifiques en Côte d'Ivoire

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Sponsor type
Research organisation

Website
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ROR
https://ror.org/03sttqc46

Funder(s)

Funder type
Not defined

Funder Name
UBS Optimus Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
The results of the study is presented to the community and local authorities during a workshop at the end of the trial. Publication of results in a high-impact peer reviewed journal is planned this year.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to the fact that ethical clearance was obtained for the purpose of the study only. If additional use is planned further ethical clearance must be obtained. The data is with the principal investigator.

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		27/02/2018	23/04/2021	Yes	No