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An integrated approach to fight parasitic worms and diarrhoea

Submission date
24/02/2014

Recruitment status
No longer recruiting

Registration date
26/03/2014

Overall study status
Completed

Last Edited
04/03/2021

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
New estimates suggest that 1.4 million people die from diarrhoea each year. Diarrhoea is still he second most important cause of death for children under 5. Although this has significantly decreased over the past 20 years, there are still 2.9 billion cases of diarrhoea each year. Furthermore, hundreds of millions of people suffer from helminthiasis (infection caused by worms called helminths) and intestinal protozoa infections, particularly in the developing world. More than half of the human population is at risk of soil-transmitted helminthiasis and schistosomiasis (alos caused by parasitic worms) over 1 billion people are infected, and the global burden is 10 million disability-adjusted life years (DALYs). The global strategy to control helminthiasis is preventive chemotherapy, that is the regular administration of anthelminthic drugs to at-risk populations. Re-infection after treatment can occur rapidly as long as access to clean water and adequate sanitation has not been improved and hygiene behaviour remains unchanged. Integrated approaches are necessary in order achieve control and elimination in the longer term in countries with limited resources.
This study deals with an integrated and sustainable approach for the control of neglected tropical diseases and diarrhoea. The aim is to assess and quantify the effect of preventive chemotherapy combined with community-led total sanitation (CLTS) and community health education programme (CHEP) on reinfection patterns of soil-transmitted helminths, schistosomes and intestinal protozoa, and diarrhoea in 40 communities in south-central Côte d Ivoire. A video-based cartoon as part of the CHEP will be developed and tested in 20 schools.

Who can participate?
All children of 20 schools (grades 3-6) and members of 40 communities (community members aged 12-24 months, 5-15 years and >15 years) with written informed consent or children aged <18 years with written informed consent from parental/legal guardian will be invited to participate in the parasitological examination, diarrhoea monitoring and the Knowledge, Attitude, Practice and Belief (KAPB) surveys. In all 40 communities, members of the community are invited to participate in the implementation of CLTS and CHEP sessions using participatory rural appraisal (PRA) methods.
What does the study involve?
In a first step, the CHEP will be developed. That includes an animated cartoon for hygiene and health that is targeted at school-aged children and a community health theatre for the entire

community. The cartoon will be screen-played to schoolchildren attending grades 3-6 in 10 schools out of 20 schools and its impact on neglected tropical diseases and defecation-related knowledge, attitude, practice and beliefs (KAPB) compared to the other 10 schools that did not see the cartoon. Before the showing the cartoon, parasitological and KAPB surveys will take place among 100 schoolchildren from grades 3-6 per school. These surveys will be repeated 12 months later.
In a second step, 40 communities will benefit from different intervention packages (integrated control packages). While all these 40 communities will receive preventive chemotherapy, 10 communities will additionally receive a CHEP intervention, another 10 will receive a CLTS intervention, and 10 communities will receive both CHEP and CLTS interventions. To increase our understanding of helminth and intestinal protozoa infection, diarrhoea frequency and schoolchildren's and communities defecation-related KAPB and the effect of CLTS and CHEP on these aspects, a number of quantitative studies will be carried out using questionnaires, key informant interviews (KIIs) and focus group discussions (FGDs). The initial parasitological examinations and KAPB assessment will take place in 30 randomly selected households in each of the 40 communities.

What are the possible benefits and risks of participating?
All participants profit from repeated de-worming with albendazole, one of the drugs of choice according to World Health Organization recommendations, and praziquantel (administration free of charge). Both treatments work well against the common soil-transmitted helminths and schistosomiasis and have good safety profiles. The interventions on health education and sanitation will improve sanitation and health profiles of the participating school classes and communities.
There are no specific risks associated with this study, although the submission of stool and urine samples by adult study participants might be perceived as shameful. Furthermore, albendazole and praziquantel used for preventive chemotherapy might result in some adverse events, but these are usually few, mild and quickly disappear.

Where is the study run from?
The study will be conducted in 20 rural primary schools of Western Côte d'Ivoire and in 40 entire communities of South-Central Côte d'Ivoire.

When is study starting and how long is it expected to run for?
The study will start in March 2014 and will run for approximately 2 1/4 years.

Who is funding the study?
The study is funded by the UBS Optimus Foundation

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
An integrated approach to fight neglected tropical diseases and diarrhoea

Study objectives
Our integrated approach, consisting of preventive chemotherapy combined with either community health education or community-led total sanitation or both, will decrease the incidence of helminth and intestinal protozoa infections and diarrhoea and improve health-related hygiene knowledge and behaviour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Basel Ethics Committee (EKBB, Switzerland), 11 November 2013, reference no. 300/13
2. Comité National dEthique et de la Recherche (CNER, Côte dIvoire), 28 November 2013, reference 76-2013/MSLS/CNER-dkn

Study design
Cluster randomized intervention trial with repeated cross-sectional parasitological and questionnaire surveys before intervention (baseline) and 12 and 24 months post-intervention (follow-up 1 + 2).

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Neglected tropical diseases (soil-transmitted helminths, schistosomes, intestinal protozoa) and diarrhoea

Interventions
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, will be given to the whole study population in the 20 schools and the 40 communities. Among the 20 schools, 10 schools will be randomly selected and will have the

animated health educational cartoon screen-played. Furthermore, while all these 40 communities will receive preventive chemotherapy, 10 communities will additionally receive a community health education programme (CHEP) intervention that includes the animated health educational cartoon that is targeted at school-aged children and a community health theatre for the entire community, another 10 communities will receive a community-led total sanitation (CLTS) intervention, and 10 communities will receive both CHEP and CLTS interventions. CHEP and CLTS interventions will be randomly assigned to communities.

Within each community 30 households will be randomly selected and their members invited for parasitological, anthropometric and KAPB investigations before the interventions and at 12 and 24 months post-intervention. Diarrhoea monitoring will as well be undertaken in these households during 24 months at a 2 week interval. At the 20 schools, only children from grades 3-6 will be invited for parasitological and KAPB assessment before intervention and 12 months after the baseline.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Reinfection rates with soil-transmitted helminths, schistosomes and intestinal protozoa and incidence of diarrhoea episodes 12 and 24 months after the baseline survey

Key secondary outcome(s))
KAPB with regard to sanitation and nutritional status of infants at baseline and 12 and 24 months after baseline

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Primary school child, aged 5-15 years (grades 3-6), male or female in the schoolbased survey
2. Infants aged between 12-24 months, children aged 5-15 years, young adults or adults aged above 15 years in the community survey
3. Written informed consent by a parent/guardian on behalf of the child younger than 18 years or written informed consent by adult participant
4. Submission of 1 urine and 1 stool sample at baseline
5. Completion of questionnaire by head of household in the community survey at baseline
6. Absence of difficult health condition as assessed by a medical doctor at baseline

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
15 years

Sex
All

Key exclusion criteria
1. Children below 5 years or above 15 years in the school based survey
2. Children below the age of 12 months or between 2 and 4 years
3. No written informed consent
4. No complete set of urine and stool sample submitted at baseline
5. No completion of questionnaire by head of household in the community survey at baseline
6. Presence of medical condition that prevents child from participating to the study

Date of first enrolment
01/04/2014

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Côte d'Ivoire

Switzerland

Study participating centre
Socinstrassse 57
Basel
Switzerland
4002

Sponsor information

Organisation

Swiss Center for Scientific Research (Cote d'Ivoire)

Funder(s)

Funder type
Charity

Funder Name
UBS Optimus Foundation (Project No 3254.01)

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
Switzerland

Results and Publications

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?
Results article	baseline results	18/02/2018	04/03/2021	Yes	No
Protocol article	protocol	12/06/2018		Yes	No