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Epidemiology and control of schistosomiasis in preschool-aged children in Côte dIvoire, with particular consideration to the efficacy and safety of crushed praziquantel tablets

Submission date
23/08/2011

Recruitment status
No longer recruiting

Registration date
07/11/2011

Overall study status
Completed

Last Edited
05/09/2014

Condition category
Infections and Infestations

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

Plain English Summary
Background and study aims
Schistosomiasis is a disease caused by parasitic worms and remains a major public health problem in Africa. The current global strategy to control schistosomiasis is to use the drug praziquantel. School-aged children (age: 6-15 years) are at highest risk of schistosomiasis, and hence praziquantel is mainly administered to this age group. However, recent studies have shown that in areas where schistosomiasis is highly prevalent, preschool-aged children (<6 years) might already be at risk of schistosomiasis, and hence should be included in regular treatments. The main aim of this study is to find out about the epidemiology (the incidence, distribution, and possible control) of schistosomiasis in preschool-aged children in two selected villages in Azaguié district, south Côte dIvoire, where schistosomiasis is highly prevalent. Children will then be treated with praziquantel, using crushed tablets. The safety and effectiveness of the treatment will be determined. Findings from our study will contribute to a better understanding of the local epidemiology of schistosomiasis in the Azaguié district and will determined whether crushed tablets are safe and effective against schistosomiasis in preschool-aged children.

Who can participate?
All children below the age of 6 years in two selected villages in Azaguié district. Parents or legal guardians of eligible children will be asked to sign an informed consent sheet.

What does the study involve?
Children will be invited to provide two stool and two urine samples for schistosomiasis diagnosis. Additionally, a single fingerprick blood sample will be taken. Finally, children will be examined by a study physician and only those deemed healthy will be enrolled for treatment with a single oral dose of praziquantel, using crushed tablets. Adverse events will be monitored within 4 hours after treatment and children will be interviewed about adverse events again 24 hours post-treatment. 3-4 weeks post-treatment, children will be re-examined using the same diagnostic approach as at baseline.

What are the possible benefits and risks of participating?
Praziquantel has been widely used over the past 30 years. It might cause some adverse events (e. g. abdominal pain, diarrhoea, vomiting), but these are usually mild and self-limiting. Treatment will be given under medical supervision. At the end of the study, the entire village population will be given praziquantel and albendazole (against soil-transmitted helminthiasis) free of charge.

Where is the study run from?
The study will be carried out in two villages in the Azaguié district, located in south Côte dIvoire.

When is the study starting and how long is it expected to run for?
The study will start in August 2011 and will run for about 6-8 weeks.

Who is funding the study?
The study is funded by the Rudolf Geigy-Stiftung zu Gunsten des Schweizerischen Tropen- und Public Health-Instituts, based in Basel, Switzerland.

Who is the main contact?
Prof. Dr. Jürg Utzinger
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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
Epidemiology and control of schistosomiasis in preschool-aged children in Côte dIvoire, with particular consideration to the efficacy and safety of crushed praziquantel tablets: a non-randomised study

Study hypothesis
1. Praziquantel (administered at 40 mg/kg oral dose using crushed tablets) is efficacious against S. mansoni and S. haematobium infections in preschool-aged children
2. Praziquantel treatment in preschool-aged children is safe

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committe,Côte dIvoire [Comité National dEthique et de la Recherche (CNER) in Côte dIvoire], 25/08/2010, ref: 4248/2010/MSHP/CNER

Study design
Non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
Schistosomiasis

Interventions
Study participants diagnosed with either S. mansoni, S. haematobium or both species concurrently will be treated with praziquantel (single 40 mg/kg oral dose, using crushed tablets)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Praziquantel

Primary outcome measure
Cure rate and egg reduction rate of S. mansoni and S. haematobium, determined 3-4 weeks post-treatment by multiple stool sampling using the Kato-Katz method and multiple urine filtration tests

Secondary outcome measures
Frequency and severity of adverse events recorded within 24 hours after drug administration

Overall study start date
25/08/2011

Overall study end date
15/10/2011

Eligibility

Participant inclusion criteria
1. Both males and females, aged less than or equal to 72 months
2. Written informed consent by parents or legal guardian
3. Submission of two stool samples of sufficient size to prepare duplicate Kato-Katz thick smears from each sample at the baseline survey
4. Submission of two urine samples of sufficient amount for urine filtration method at the baseline survey
5. Provision of single fingerprick blood sample for malaria rapid diagnostic test and haemoglobin level assessment
6. Absence of major systemic illnesses, as assessed by medical personnel on the day of treatment

Participant type(s)
Patient

Age group
Child

Upper age limit
72 Months

Sex
Both

Target number of participants
350

Participant exclusion criteria
1. Children aged more than 72 months
2. No written informed consent provided by by parents or legal guardian
3. Submission of less than two stool samples of sufficient size to prepare duplicate Kato-Katz smears from each sample at the baseline or follow-up survey
4. Submission of less than two urine samples of sufficient amount for urine filtration method at

the baseline survey
5. No provision of fingerprick blood sample for malaria rapid diagnostic test and haemoglobin level assessment
6. Presence of any abnormal medical condition, as judged by the medical personnel on the day of treatment (e.g. clinical malaria)
7. Recent anthelminthic treatment (within 4 weeks)
8. Participation in other studies

Recruitment start date
25/08/2011

Recruitment end date
15/10/2011

Locations

Countries of recruitment
Côte d'Ivoire

Switzerland

Study participating centre
Department of Epidemiology and Public Health
Basel
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Sponsor information

Organisation
Swiss Tropical and Public Health Institute (Switzerland)

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Sponsor type
Research organisation

Website

http://www.swisstph.ch/

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Government

Funder Name
Rudolf Geigy Foundation for the benefit of the Swiss Tropical Institute and Public Health [Rudolf Geigy-Stiftung zu Gunsten des Schweizerischen Tropen- und Public Health-Instituts] (Switzerland)

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?
Results article	results	01/08/2012		Yes	No