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Dose-finding of oxantel pamoate in school-aged children infected with Trichuris trichiura on Pemba, United Republic of Tanzania

Submission date
08/10/2014

Recruitment status
No longer recruiting

Registration date
12/11/2014

Overall study status
Completed

Last Edited
22/09/2015

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
Trichuris trichiura (whipworm) is a helminthic parasite, transmitted through soil. Whipworm infection is a neglected tropical disease and causes a huge burden worldwide. The available drugs have limitations. This study will compare the effectiveness of six different doses of a drug, oxantel pamoate, compared to a placebo (dummy) drug in school-aged children infected with T. trichiura, in order to find out the right dose of the drug.

Who can participate?
Children studying in the participating primary schools.

What does the study involve?
To examine whether children are infected, two stool samples will be collected and analysed. All children who are positive for T. trichiura will be randomly allocated to the seven different treatment groups and receive either one of six different doses of the drug or the placebo treatment. Children are interviewed to find out if they had any side effects. After three weeks, children will provide another two stool samples to see whether they got cured and to calculate egg reduction rates.

What are the possible benefits and risks of participating?
At the end of the study, children remaining positive for the infection will be treated according to national guidelines. All the working procedures and examinations during this study do not bear any particular additional risks. Side effects are mild and include stomach ache and dizziness.

Where is the study run from?
Two primary schools on Pemba Island, United Republic of Tanzania.

When is the study starting and how long is it expected to run for?
October 2014 to December 2014.

Who is funding the study?
Swiss National Science Foundation (Switzerland).

Who is the main contact?
Prof Jennifer Keiser
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
No

Study information

Scientific Title
Dose-finding of oxantel pamoate in school-aged children infected with Trichuris trichiura on Pemba, United Republic of Tanzania: a randomized controlled phase 2a trial

Acronym
Oxpatri

Study objectives
Different doses of oxantel pamoate have not yet been sufficiently studied in infected school-aged children. Dosing regimens in humans are empirical.

Ethics approval required
Old ethics approval format

Ethics approval(s)
EKNZ 2014-315 (Switzerland), ZAMREC/0002/August/2014 (Zanzibar, Tanzania)

Study design
Randomized controlled phase 2a dose finding trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Trichuriasis

Interventions
Two stool samples will be collected on two consecutive days. The medical history of the participating schoolchildren will be assessed with a standardized and previously used questionnaire, in addition to a clinical examination carried out by the study physician on the treatment day. All children positive for T. trichiura will be randomly assigned (computer-generated stratified block randomization code) to one of the seven treatment arms: 5, 10, 15, 20, 25, 30 mg/kg oxantel pamoate and placebo. School-aged children will also be interviewed before treatment, 2 and 24 hours after treatment about the occurrence of adverse events. The efficacy of the treatment will be determined 21-26 days post-treatment by collecting another two stool samples. All stool samples will be examined with duplicated Kato-Katz thick smears.

1. 400 mg placebo
2. Oxantel pamoate 5 mg/kg
3. Oxantel pamoate 10 mg/kg
4. Oxantel pamoate 15 mg/kg
5. Oxantel pamoate 20 mg/kg
6. Oxantel pamoate 25 mg/kg
7. Oxantel pamoate 30 mg/kg

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Oxantel pamoate

Primary outcome(s)
1. Cure rate (CR) and egg reduction rate (ERR) against T. trichiura: 14-21 days post-treatment
2. Safety/adverse events: 3 hours and 24 hours post-treatment

Key secondary outcome(s))
CR and ERR against A. lumbricoides and hookworms

Completion date
29/11/2014

Eligibility

Key inclusion criteria

1. Written informed consent signed by parents and/or legal guardian; and oral assent by children
2. Able and willing to be examined by a study physician at the beginning of the study
3. Able and willing to provide two stool samples at the beginning (baseline) and approximately three weeks after treatment (follow-up)
4. Positive for T. trichiura eggs in the stool
5. Absence of major systemic illnesses (e.g. cancer, diabetes, clinical malaria or hepato-splenic schistosomiasis) as assessed by a medical doctor, upon initial clinical assessment
6. No known or reported history of chronical illness as cancer, diabetes, chronic heart, liver or renal disease
7. No recent anthelminthic treatment (within past 4 weeks)
8. No known allergy to study medications

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. No written informed consent by parents and/or legal guardian
2. Presence of any abnormal medical condition, judged by the study physician
3. History of acute or severe chronic disease such as cancer, diabetes, chronic heart, liver or renal disease
4. Recent use of anthelminthic drug (within past 4 weeks)
5. Attending other clinical trials during the study
6. Negative diagnostic result for T. trichiura (absence of helminth eggs in stool)

Date of first enrolment
16/10/2014

Date of final enrolment
29/11/2014

Locations

Countries of recruitment
Switzerland

Tanzania

Study participating centre
Swiss Tropical and Public Health Institute
Basel

Switzerland
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Sponsor information

Organisation
Swiss National Science Foundation (SNSF) (Switzerland)

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Research organisation

Funder Name
Swiss National Science Foundation (Switzerland)

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No