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Albendazole-oxantel, albendazole-ivermectin, albendazole-mebendazole, and mebendazole in the treatment of whipworm infections

Submission date
16/07/2013

Recruitment status
No longer recruiting

Registration date
01/08/2013

Overall study status
Completed

Last Edited
08/11/2016

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parasitic worm infections are widespread and they affect the health and wellbeing of mainly rural communities in the developing world. More than one billion people are infected with one or several of the common soil-transmitted helminths (STH). Treatment of STH infection with a single oral dose of current drugs is unsatisfactory. Several drug combinations have shown to be more effective than the currently recommended standard drug mebendazole. In this study we would like to assess various drug combinations and find out which combination should be recommended for the treatment of STH infection. In addition, we would like to monitor the effect of the three drug combinations on other parasitic infections and to find out the clinical benefit of the tested drug combinations based on history of self-reported signs and symptoms, physical examination and blood tests.

Who can participate?
Children aged 6 to 14 years can participate in this study.

What does the study involve?
Children will be given a written consent form and two containers. If willing to participate they shall return the consent form signed by their parents and the two containers filled with a fresh morning stool sample each. Stool samples will be tested for STH eggs. Children diagnosed positive for infection will be randomly allocated to one of the four treatment groups. Before receiving treatment, children will be checked by a physician. A finger prick blood sample will be taken from children before treatment. Children will be interviewed 2 hours and 24 hours after treatment about the occurrence of side effects. The effectiveness of the treatment will be determined 19-25 days after treatment, testing stool samples for STH eggs. About three months after treatment, when the clinical benefits are more likely to be measurable, children will again undergo a rigorous clinical examination. A finger prick blood sample will again be tested for hemoglobin levels and a questionnaire focusing on signs and symptoms will be given. To check if children were re-infected they will be asked to provide more stool samples which will be examined for STH eggs.

What are the possible benefits and risks of participating?
All children participating will benefit from a free treatment of a potentially active drug against STH. At the end of the study, all children diagnosed as infected with a parasite will be treated according to national guidelines. If the prevalence of any parasite is over 50%, all children in the school will be treated according to national guidelines. In general, few and mild side effects are expected, the most common being stomach pain, diarrhea (watery stool), nausea, headache and dizziness.

Where is the study run from?
The study will be carried out at two schools on Pemba Island (Public Health Laboratory-Ivo de Carneri), United Republic of Tanzania.

When is the study starting and how long is it expected to run for?
August 2013 to December 2013

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy and safety of albendazole-OXantel pamoate, albendazole-mebendazole, albendazole-IVermectin and single MEBendazole in the treatment of Trichuris trichiura and concomitant Soil-Transmitted Helminth infections in Pemba: a randomized controlled trial

Acronym
OXIVMEB-STH

Study objectives
The three drug combinations (i.e. albendazole-oxantel pamoate, albendazole-mebendazole, and albendazole-ivermectin) achieve higher cure and egg reduction rates against T. trichiura infections compared to single-dose mebendazole (500 mg).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Basel (Ethikkomission beider Basel [EKBB]), 02/07/2013, ref: 123/13
2. Ministry of Health and Social Welfare, 01/07/2013, ref: ZAMREC/0001/JUNE/013

Study design
Randomized controlled trial with four treatment arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Group 1:
Albendazole (400 mg) + ivermectin (200 µg/kg)

Group 2:
Albendazole (400 mg) + mebendazole (500 mg)

Group 3:
Albendazole (400 mg) + oxantel pamoate (20 mg/kg)

Group 4:
Mebendazole (500 mg)

All interventions will be done on one day (single dose). This means that children from treatment group 1-3 receive albendazole together with either ivermectin, mebendazole, or oxantel pamoate, while treatment group 4 receives mebendazole.

Baseline and follow-up will last a maximum of 5 days (two stool samples collected over maximum 5 days).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Albendazole-oxantel, albendazole-ivermectin, albendazole-mebendazole, mebendazole

Primary outcome measure
Efficacy (cure rate and egg reduction rate) against T. trichiura

Secondary outcome measures
1. Adverse events observed with study drugs (before treatment, 2 and 24 hours after treatment).
2. The effect of the three drug combinations on infections with S. stercoralis, A. lumbricoides, A. duodenale, N. americanus. (Effect will be measured as reduction of eggs per gram of faeces [A. lumbricoides, A. duodenale, N. americanus] or if living larvae disappear after treatment from stool sample [S. stercoralis]. Measured at baseline and 3 weeks after treatment).
3. The clinical benefit of the tested drug combinations based on history of self-reported signs and symptoms, physical examination, and hemoglobin levels. (Measured at baseline [physical examination, questionnaire about general health using the visual analogue scale, and finger prick blood samples], 3 weeks after treatment [questionnaire about general health using the visual analogue scale], 3 months after treatment [physical examination, questionnaire about general health using the visual analogue scale, and finger prick blood samples].

Overall study start date
15/08/2013

Completion date
15/12/2013

Eligibility

Key inclusion criteria
1. Written informed consent signed by parents and/or legal guardian; and oral assent by children (aged 6-14 years)
2. Able and willing to be examined by a study physician and answer a questionnaire about signs

and symptoms at the beginning of the study, 3 weeks and 3 months after treatment
3. Able and willing to provide two stool samples at the beginning of the study, 3 weeks and 3 months after treatment
4. Able and willing to provide a urine sample and a finger prick blood sample before treatment and 3 months after treatment
5. Positive for T. trichiura (presence of eggs in stool) at the baseline parasitology survey
6. Absence of major systemic illnesses (e.g. clinical malaria or hepato-splenic schistosomiasis) as assessed by a medical doctor, upon initial clinical assessment
7. No known or reported history of chronic illness such as cancer, diabetes, heart, liver or renal disease
8. No known allergy to study medications

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
440

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 drugs (within the past 4 weeks)
5. Attending other clinical trials during the study
6. Negative diagnostic result for T. trichiura (absence of eggs in stool) at baseline parasitological survey

Date of first enrolment
15/08/2013

Date of final enrolment
15/12/2013

Locations

Countries of recruitment
Switzerland

Tanzania

Study participating centre
Swiss Tropical and Public Health Institute
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Sponsor information

Organisation
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Sponsor type
Research organisation

Website
http://www.swisstph.ch/

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Research organisation

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

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, SNF, SNSF, FNS

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
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	01/03/2015		Yes	No
Results article	results	02/03/2016		Yes	No