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Oxantel and oxantel-albendazole in the treatment of whipworm and hookworm infections

Submission date
15/08/2012

Recruitment status
No longer recruiting

Registration date
22/08/2012

Overall study status
Completed

Last Edited
12/06/2014

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
Between 600 and 800 million people are infected with one or several of the common soil-transmitted helminths, which are Ascaris lumbricoides, Trichuris trichiura, and hookworms. The current strategy to control soil-transmitted helminths is to administer either albendazole or mebendazole to people at risk. However, these drugs are not effective or only partially effective against T. trichiura and hookworm. Therefore new safe drugs are needed. The aim of this study is to compare the effectiveness and safety of albendazole, mebendazole, oxantel pamoate and an albendazole-oxantel pamoate combination against infections with T. trichiura and hookworm.

Who can participate?
Children aged 6-14 infected with T. trichiura or hookworm, or both.

What does the study involve?
Two stool samples will be collected from school-aged children until 380 cases of T. trichiura and /or hookworm infections have been identified. Positive tested children will be randomly assigned to one of the following four treatment groups: group 1 will receive oxantel pamoate on the first day and albendazole and a placebo (dummy) tablet on the next day. Group 2 will receive oxantel pamoate on day 1 and two placebo tablets on day 2. Group 3 will receive a placebo tablet on day 1 and one tablet of albendazole plus a placebo tablet on the next day. Group 4 will be administered a placebo tablet on day 1 and one mebendazole tablet plus one placebo tablet on day 2. Adverse effects will be assessed at 3 and 24 hours after each treatment.

What are the possible benefits and risks of participating?
The three drugs which are being compared are well known and have few adverse effects. All enrolled children will benefit from a free treatment against soil-transmitted helminths.

Where is the study run from?
The study will be carried out in three schools on Pemba, Tanzania and will be conducted by the Public Health Laboratory Ivo de Carneri (Tanzania).

When is the study starting and how long is it expected to run for?
The study will take place from September to November 2012.

Who is funding the study?
The study will be funded by the Medicor Foundation (Liechtenstein).

Who is the main contact?
Jennifer Keiser, Swiss Tropical and Public Health Institute, Basel, Switzerland.

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Efficacy and safety of albendazole-oxantel combined and single oxantel albendazole, and mebendazole, in the treatment of Trichuris trichiura and hookworm infections in Pemba: a randomized, double blind trial

Acronym
OXAALB-STH

Study objectives
Oxantel-albendazole reaches higher cure rates against T. trichiura and hookworm infections than the standard treatments (mebendazole).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Basel [Ethikkomission beider Basel (EKBB)], 20/01/2012, ref: 390/11
2. Ministry of Health and Social Welfare, 27/07/2012, ref: ZAMREC/0001/JAN/011

Study design
Double-blind randomized controlled trial with four treatment arms

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
T. trichiura or/and hookworm infections

Interventions
Group 1:
Day 1: 20 mg/kg oxantel pamoate; Day 2: 1 albendazole tablet plus 1 mebendazole matching placebo

Group 2:
Day 1: 20 mg/kg oxantel pamoate; Day 2: 1 albendazole matching placebo plus 1 mebendazole matching placebo

Group 3:
Day 1: 20 mg/kg oxantel pamoate placebo; Day 2: 1 albendazole tablet plus 1 mebendazole matching placebo

Group 4:
Day 1: 20 mg/kg oxantel pamoate placebo; Day 2: 1 mebendazole tablet plus 1 albendazole matching placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oxantel, oxantel-albendazole

Primary outcome(s)
Cure rates and egg reduction rates 3 weeks after treatment. For diagnosis two stool samples will be collected before and after treatment. From each stool sample duplicate Kato-Katz thick smears will be examined.

Key secondary outcome(s))
Adverse events will be assessed 3 and 24 hours after each day of treatment.

Completion date
26/10/2012

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 and at the end of the study (3 weeks post-treatment)
3. Able and willing to provide two stool samples at the beginning and at the end of the study
4. Positive for T. trichiura or hookworm, or both STH concurrently (presence of helminth eggs in 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 chronic illness such 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 and/or hookworm (absence of helminth eggs in stool)

Date of first enrolment
10/09/2012

Date of final enrolment
26/10/2012

Locations

Countries of recruitment
Switzerland

Tanzania

Study participating centre
University of Basel
Basel
Switzerland
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Sponsor information

Organisation
Medicor Foundation (Liechtenstein)

ROR
https://ror.org/0469pxf24

Funder(s)

Funder type
Charity

Funder Name
Medicor Foundation (Liechtenstein)

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	results	13/02/2014		Yes	No