

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

Submission date 15/08/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/06/2014	Condition category Infections and Infestations	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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 [Ethikkommission 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

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 measure

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.

Secondary outcome measures

Adverse events will be assessed 3 and 24 hours after each day of treatment.

Overall study start date

10/09/2012

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 anthelmintic treatment (within past 4 weeks)
8. No known allergy to study medications

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

650

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 anthelmintic 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

4051

Sponsor information

Organisation

Medicor Foundation (Liechtenstein)

Sponsor details

Landstrasse 11

Postfach 141

Triesen

Liechtenstein

9495

Sponsor type

Charity

Website

<http://www.medicor.li/>

ROR

<https://ror.org/0469pxf24>

Funder(s)

Funder type

Charity

Funder Name

Medicor Foundation (Liechtenstein)

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	13/02/2014		Yes	No