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Efficacy and safety of moxidectin alone and in combination against Trichuris trichiura infection: a randomised controlled trial

Submission date
24/02/2017

Recruitment status
No longer recruiting

Registration date
28/02/2017

Overall study status
Completed

Last Edited
07/10/2020

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 worms are organisms that live in the intestine and feed off their living hosts. They are among the most common type of infections worldwide, especially in poor and deprived communities. They are spread by eggs present in human faeces which in turn contaminate soil in areas where sanitation is poor. An infection can cause malnutrition, physical and mental retardation, and reduced work performance in older age. On Pemba Island most children are infected with one or even two or three different types of parasitic worms, despite the fact that preventive treatment with anti-parasite medications such as praziquantel and albendazole is carried out yearly. The existing drugs albendazole and mebendazole, which are widely used in preventive drug treatment, have been found to be ineffective against whipworm (a type of parasitic worm) infections. Therefore there is a need to discover and develop treatment alternatives. Moxidectin is a drug which kills parasitic worms and is used to prevent and control heartworm and intestinal worms in animals. It is currently under approval for use in humans. The aim of this study is to look at the efficacy and safety of moxidectin alone and in combination against parasitic worm infections.

Who can participate?
Patients aged 12-18 years who have parasitic worms.

What does the study involve?
Participants are randomly allocated to one of four groups. Those in the first group receive a single dose of moxidectin to take by mouth, those in the second group are given a single dose of moxidectin and tribendimidine, those in the third group are given a single dose of moxidectin and albendazole and those in the fourth group are given a single dose of albendazole and oxantel pamoate. For all participants, two stool samples are collected if possible on two consecutive days or otherwise within a maximum of 5 days. The medical history of the participants is assessed with a standardized and previously used questionnaire, in addition to a clinical examination carried out by the study physician on the treatment day. Participants are

also interviewed before treatment, 1, 3, 24 and 48 hours after treatment about the occurrence of side effects. The efficacy of the treatment is determined 21 days post-treatment by collecting other two stool samples and testing for the presence of parasitic worm eggs.

What are the possible benefits and risks of participating?
Participants benefit from receiving free treatment which could rid them of their parasitic worm infection. The drugs used are safe and have been already used in previous trials with adolescents of the same age range. Participants take the risk of having side effects, but will be closely monitored shortly after assumption and for the following two days.

Where is the study run from?
Public Health Laboratory Ivo de Carneri (Tanzania)

When is the study starting and how long is it expected to run for?
May 2016 to December 2017

Who is funding the study?
Thrasher Foundation (USA)

Who is the main contact?
Professor Jennifer Keiser
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
V 0.1

Study information

Scientific Title

Efficacy and safety of moxidectin plus albendazole, moxidectin plus tribendimidine, and moxidectin alone versus albendazole plus oxantel pamoate against Trichuris trichiura and concomitant soil-transmitted helminth infections: a randomised controlled trial

Study objectives
A combination of moxidectin with albendazole or tribendimidine demonstrates high efficacy against Trichuris trichiura and concomitant soil-transmitted helminth infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics committee of Northwestern and Central Switzerland (EKNZ), 21/02/2017, ref: 2016-00839
2. Zanzibar Medical Research and Ethical Committee (Tanzania), ref: ZAMREC/0001/February 2017

Primary study design
Interventional

Study design
Single-blind randomosed controlled drug combination trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infection with Trichuris trichiura and other soil-transmitted helminths

Interventions
Study participants eligible for treatment will be randomly assigned to one of the four treatment arms using a computer-generated stratified block randomization code. The random allocation sequence with varying random blocks of seven or fourteen will be provided by a statistician.

Group 1: Participants receive a single oral dose of moxidectin 8 mg
Group 2: Participants receive a single oral dose of moxidectin 8 mg plus tribendimidine 400 mg
Group 3: Participants receive a single oral dose of moxidectin 8 mg plus albendazole 400 mg
Group 4: Participants receive a single oral dose of albendazole 400 mg plus oxantel pamoate 25 mg/kg

The treatment will be administered on one day only and follow up will be conducted for all treatment arms 21 days after treatment.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)

1. Moxidectin 2. Tribendimidine 3. Albendazole 4. Oxantel pamoate

Primary outcome(s)
The egg reduction rates (ERRs) of moxidectin and the combinations moxidectin/tribendimidine and moxidectin/albendazole against T. trichiura will be assessed using the quadruple Kato-Katz method 21 days after treatment.

Key secondary outcome(s)
1. Efficacy in terms of CR against T. trichiura and CR and ERR against co-infections using the quadruple Kato-Katz method 21 days after treatment
2. Safety will be assessed with evaluation of the treated subjects at 3, 24 and 48 hours after treatment

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Written informed consent signed by participants (if 18 years old), parents and/or legal guardian; and oral assent by participants
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 one and 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 organ failure) as assessed by a medical doctor, upon initial clinical assessment
6. No known or reported history of chronic illness as cancer, diabetes, chronic heart, liver or renal disease.
7. No recent anthelminthic treatments (within past 2 months)
8. No known allergy to study medications
9. Age 12-18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. No written informed consent by participants, 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 past 2 months)
5. Attending other clinical trials during the study
6. Negative diagnostic result for T. trichiura eggs in stool samples
7. Age below 12 years

Date of first enrolment
15/03/2017

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
Tanzania

Study participating centre
Public Health Laboratory Ivo de Carneri
PO Box 122 Wawi, Chake Chake
Pemba, Zanzibar (Tanzania)
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Tanzania
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Sponsor information

Organisation
Swiss Tropical and Public Health Institute

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Charity

Funder Name
Thrasher Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Jennifer Keiser (jennifer.keiser@unibas.ch)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No
Results article	results	02/10/2020	07/10/2020	Yes	No