ISRCTN83836427 https://doi.org/10.1186/ISRCTN83836427

Assessing the efficacy and safety of albendazole, nitazoxanide and albendazole-nitazoxanide in the treatment of Trichuris trichiura and other Soil Transmitted Helminth infections in Pemba, Tanzania

Submission date 10/05/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/06/2011	**Overall study status** Completed	
Last Edited 23/09/2016	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Soil-transmitted helminths are intestinal worms that infect humans and are transmitted through contaminated soil. Between 600 and 800 million people are infected with one or several of the common soil-transmitted helminths. There is a pressing need for new drugs against soil-transmitted helminth infection. At present, there are four drugs on the World Health Organization (WHO) model list of essential medicines and they have been widely and effectively used against STH infections for three decades or more. The aim of this study is to assess the effectiveness and safety of oral albendazole, nitazoxanide and a nitazoxanide-albendazole combination against STH infection.

Who can participate?
Children aged 6 - 12 in Pemba, Tanzania

What does the study involve?
Participants are randomly allocated to be treated with either oral albendazole, nitazoxanide, or a nitazoxanide-albendazole combination. At the start and the end of the study participants' stool samples are examined and the number of helminth eggs per gram of stool is measured. All participants are closely monitored for illness during the period of drug treatment. Participants who report side effects are examined carefully by the study doctor and, when necessary, action is taken. At the end of the study all participants are treated with albendazole and any other infections are diagnosed according to the national treatment guidelines for district hospitals.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Swiss Tropical and Public Health Institute (Switzerland)

When is the study starting and how long is it expected to run for?
June 2011 to July 2011

Who is funding the study?
1. University of Basel (Switzerland)
2. Vontobel Foundation (Switzerland)

Who is the main contact?
Prof. Jennifer Keiser

Contact information

Type(s)
Scientific

Contact name
Prof Jennifer Keiser

Contact details
Swiss Tropical and Public Health Institute
University of Basel
Socinstrasse 57
Basel
Switzerland
4002

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Nitazoxanide, albendazole and nitazoxanide plus albendazole, in the treatment against T. trichiura and other Soil Transmitted Helminth infections in a placebo controlled trial in Pemba, Tanzania a randomized double blind trial

Acronym
NTZALB-STH

Study objectives
An albendazole - nitazoxanide combination achieves a higher efficacy against T. trichiura than single albendazole

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Basel, 15/09/2010, ref: 225/10
2. Ministry of Health and Social Welfare (MoHSW) of Zanzibar, 31/08/2010, Ref: ZAMEC/0001/010

Study design
Randomised controlled trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Infection with soil-transmitted helminths (i.e. T. trichiura, A. lumbricoides, hookworms)

Interventions
1. Combination of albendazole (400mg) plus placebo
2. Combination of nitazoxanide (1000mg) plus placebo
3. Combination of albendazole (400mg) plus nitazoxanide (1000mg)
4. Two tablets of placebo
5. Because the drug interaction between nitazoxanide and albendazole is not known, the two drugs will be distributed on subsequent days
6. Since albendazole and nitazoxanide have a half life time of 7 hours and 8-12 hours, respectively, no interaction between the drugs should occur when consumed on two subsequent days
At the end of the study, all children positive for soil-transmitted helminths will receive one tablet of albendazole.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Albendazole, nitazoxanide

Primary outcome measure
Cure rates and egg reduction rates three weeks after treatment:
1. For diagnosis 2 stool samples will be collected before and after treatment
2. From each stool sample 2 Kato-Katz thick smears will be examined
3. Additionally 2g of stool will be preserved for later diagnosis with the FLOTAC technique and ether concentration method

Secondary outcome measures
Adverse events due to specific treatment:
1. Participants will be monitored 1 hour after treatment
2. 24 hours after each day of treatment they will be asked with a standard questionnaire for adverse events

Overall study start date
06/06/2011

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Written informed consent signed by parents and/or legal guardian
2. Male or female, aged 6 - 12 years
3. Able and willing to be examined by a study physician at the beginning and at the end of the study (3 weeks post-treatment)
4. Able and willing to provide 2 stool samples at the beginning and at the end of the study
5. Absence of major systemic illnesses (e.g. cancer, diabetes, clinical malaria or hepato-splenic schistosomiasis) as assessed by the 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 treatment (within past 4 weeks)
8. No pregnancy

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. No written informed consent by parents/legal guardian and child
2. Presence of any abnormal medical condition, judged by the study physician
3. History of acute or severe chronic disease.(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. Pregnancy

Date of first enrolment
06/06/2011

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Switzerland

Tanzania

Study participating centre
Swiss Tropical and Public Health Institute
Basel
Switzerland
4002

Sponsor information

Organisation
University of Basel (Switzerland)

Sponsor details
University of Basel
Petersplatz 1
CH-4003

Basel
Switzerland
4003

Sponsor type
University/education

Website
http://www.unibas.ch/

ROR
https://ror.org/02s6k3f65

Funder(s)

Funder type
University/education

Funder Name
Universität Basel

Alternative Name(s)
UniBas, University of Basel, Universitas Basiliensis, Die Universität Basel, UB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Funder Name
Vontobel-Stiftung

Alternative Name(s)
Vontobel Foundation

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