

# 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

<b>Submission date</b> 10/05/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 23/09/2016	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## 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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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 anthelmintic treatment (within past 4 weeks)
8. No pregnancy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

12 years

**Sex**

All

**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 anthelmintic 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)

### ROR

<https://ror.org/02s6k3f65>

## Funder(s)

### Funder type

University/education

### Funder Name

Universität Basel

### Alternative Name(s)

University of Basel, UniBas, Die Universität Basel, Universitas Basiliensis, 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**

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration