

# Efficacy and safety of anti-worm drugs in schoolchildren in Zanzibar, Tanzania

<b>Submission date</b> 18/02/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 24/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/09/2012	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**  
Efficacy and safety of albendazole and mebendazole as single-dose or in combination with ivermectin against soil-transmitted helminth infections, particularly *Trichuris trichiura*, in schoolchildren in Zanzibar, Tanzania: a randomised controlled trial

**Acronym**

Alben-Meben-Ivermect-Zanzibar

### **Study objectives**

1. Combination therapy with either albendazole or mebendazole plus ivermectin is more efficacious against *Trichuris trichiura* than single therapy with either albendazole or mebendazole
2. Current efficacy of either albendazole or mebendazole (single dose) is low due to the long-term administration of these drugs in the national helminth control programme in Zanzibar
3. The FLOTAC® technique is more sensitive than the Kato-Katz technique for helminth egg detection

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethikkommission beider Basel EKBB gave approval on the 15th January 2009 (ref: 13/09)

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Soil-transmitted helminthiasis

### **Interventions**

Four treatment groups as follows:

1. Single-dose albendazole; children will receive one tablet of albendazole (400 mg) and a placebo resembling ivermectin (number of tablets according to weight)
2. Mebendazole; children will receive a single dose of mebendazole (500 mg) and a placebo resembling ivermectin (number of tablets according to weight)
3. Albendazole plus ivermectin; children will receive one tablet of albendazole (400 mg) plus ivermectin tablets according to their weight (200 µg/kg)
4. Mebendazole plus ivermectin; children will receive one tablet of mebendazole (500 mg) plus ivermectin tablets according to their weight (200 µg/kg)

The treatment for the four arms will be administered on a single day; follow-up is 3 - 4 weeks post-treatment.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Albendazole, mebendazole, ivermectin

**Primary outcome(s)**

1. Cure rate of *Trichuris trichiura* infection (percentage of children with egg counts greater than 0 before treatment who become negative after treatment)
2. Egg reduction rate of *Trichuris trichiura* infection (reduction in egg count in a measured quantity of faeces following treatment in those not cured)

**Key secondary outcome(s)**

Cure rate and egg reduction rate of *Ascaris lumbricoides* and hookworm

**Completion date**

31/05/2009

**Eligibility****Key inclusion criteria**

1. Aged greater than or equal to 5 years, both sexes
2. Submission of one stool sample of sufficient size to perform a total of two thick Kato-Katz smears at the baseline parasitological survey
3. Submission of one stool sample of sufficient size to perform a total of two thick Kato-Katz smears at the day of treatment
4. Infection with *Trichuris trichiura* as determined with the Kato-Katz method at the baseline survey. Additionally, also children with *A. lumbricoides* and/or hookworm infections will be included in one of the four treatment arms.
5. For females, not pregnant, as verbally assessed by medical personnel on the day of treatment
6. Absence of major systemic illnesses, as assessed by female medical personnel on the day of treatment
7. No anthelmintic treatment in the past 4 weeks, as verbally confirmed by the participant at the baseline survey
8. Written informed consent by the parent/legal guardian

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

5 years

**Sex**

All

**Key exclusion criteria**

1. No stool sample given at baseline survey or day of treatment
2. No infection with *T. trichiura*, *A. lumbricoides* and/or hookworm at baseline
3. Subjects with fever or other signs of acute illness
4. Subjects with severe neurological disorder

5. Subjects with severe liver disorder
6. Pregnant schoolgirls
7. Recent history of anthelmintic treatment
8. Consent not given

**Date of first enrolment**

01/03/2009

**Date of final enrolment**

31/05/2009

## Locations

**Countries of recruitment**

Switzerland

Tanzania

**Study participating centre**

Department of Public Health and Epidemiology

Basel

Switzerland

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## Sponsor information

**Organisation**

Swiss Tropical Institute (STI) (Switzerland)

**ROR**

<https://ror.org/03adhka07>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Commission for Research Partnerships with Developing Countries (KFPE) (Switzerland)

# 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?
<a href="#">Results article</a>	results	15/12/2010		Yes	No
<a href="#">Results article</a>	results	12/04/2011		Yes	No
<a href="#">Results article</a>	results	01/04/2012		Yes	No