

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

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 measure

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)

Secondary outcome measures

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

Overall study start date

01/03/2009

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

Age group

Child

Lower age limit

5 Years

Sex

Both

Target number of participants

2000 children screened for helminth infections; ~600 children treated with anthelmintic drugs

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)

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Sponsor type

Research organisation

Website

<http://www.sti.ch>

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

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	15/12/2010		Yes	No
Results article	results	12/04/2011		Yes	No
Results article	results	01/04/2012		Yes	No