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

Submission date	Recruitment status	[X] Prospectively registered
18/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/09/2012	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 that single therapy with either albendazole or mebendazole
2. Current efficacy of either albendazole or mebendazole (single dose) is low due 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 anthelminthic 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 anthelminthic 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
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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?
Results article	results	15/12/2010		Yes	No
Results article	results	12/04/2011		Yes	No
Results article	results	01/04/2012		Yes	No