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# Safety and efficacy of single-dose and triple-dose albendazole and mebendazole against soil-transmitted helminth infections in humans

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 10/11/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/11/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/04/2012 | 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# Study information

## Scientific Title
Safety and efficacy of single-dose and triple-dose albendazole and mebendazole against soil-transmitted helminth infections in humans: open-label randomised-controlled trial in China

## Study objectives
1. Both albendazole and mebendazole are safe for treating common soil-transmitted helminth infections in humans
2. Single-dose oral albendazole and single-dose oral mebendazole are both highly active against Ascaris lumbricoides, and result in high faecal egg count reduction rates for hookworm and Trichuris trichiura
3. Single-dose oral albendazole is more efficacious than single-dose oral mebendazole against hookworm infections
4. Triple-dose oral albendazole and triple-dose oral mebendazole are significantly more efficacious against T. trichiura than single-dose oral regimens

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Ethics Committee of Basel (Ethikkommission beider Basel [EKBB]), approved on the 23rd September 2008 (ref: 294/08)
2. Academic Board of the National Institute of Parasitic Diseases (IPD), Chinese Centre for Disease Control and Prevention (China CDC), approved on the 17th September 2008 (ref: 2008091701)

## Study design
Community-based, phase IV, open-label/single-blind, 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 below to request a patient information sheet

## Health condition(s) or problem(s) studied
Soil-transmitted helminth infections (Ascaris lumbricoides, Trichuris trichiura, hookworms)

## Interventions

Stool collection will be carried out for baseline parasitological assessment (two stools /participant, each stool tested for the presence of helminth eggs by the Kato-Katz [2 slides /stool] and FLOTAC method).

The participants will be randomly allocated to the following four trial arms:
1. Albendazole (oral) single dose: 400 mg
2. Mebendazole (oral) single dose: 500 mg
3. Triple-dose albendazole (oral): 400 mg daily for 3 days
4. Triple-dose mebendazole (oral): 500 mg daily for 3 days

The participants are blinded regarding which drug they receive but not regarding which treatment schedule they belong to (1 or 3 day treatment) since no placebos are used. The investigators are aware of drug type and schedule at each stage of the trial.

Adverse drug-related events will be monitored for 24 hours post-application. Stool collection will be repeated for parasitological treatment efficacy assessment (two stools/participant, each stool tested for the presence of helminth eggs by the Kato-Katz [2 slides/stool] and FLOTAC method).

Details of Joint Sponsor:
National Institute of Parasitic Diseases
Chinese Centre for Disease Control and Prevention
207 Rui Jin Er Road
Shanghai 200025
China
Tel: +86 (0)136 7161 6056

## Intervention Type
Other

## Phase
Phase IV

## Primary outcome measure
Cure rates of single-dose and triple-dose oral albendazole and mebendazole for treating common soil-transmitted helminth (STH) infections, especially hookworms, assessed at 2 - 3 weeks post-treatment.

## Secondary outcome measures
1. Safety of single-dose and triple-dose oral albendazole and mebendazole against common STH infections
2. Egg-reduction rates of single-dose and triple-dose oral albendazole and mebendazole against common STH infections

Assessed at 2 - 3 weeks post-treatment.

## Overall study start date
01/11/2008

## Completion date
31/01/2009

# Eligibility

### Key inclusion criteria
1. Age: greater than or equal to 5 years old
2. Sex: males and females
3. Residency: resident of Nongyang village in Menghai county, Yunnan province, Peoples Republic of China
4. Registration, participation: signing of written informed consent sheet (5 - 17 year olds: additional written approval by parents or legal guardians), willingness to comply with study procedures (stool submission, drug treatment, alcohol abstinence at day of treatment)
5. Absence of systemic or chronic diagnosed or perceivable illness as assessed by medical personnel upon enrolment and again at each day of treatment
6. Females: not pregnant (as verbally assessed by female medical personnel upon enrolment and again at each day of treatment)

### Participant type(s)
Patient

### Age group
Other

### Sex
Both

### Target number of participants
370 (max. 400)

### Key exclusion criteria
1. Age: less than 5 years
2. Residency: not a permanent resident of Nongyang village in Menghai county, Yunnan province, Peoples Republic of China
3. Registration, participation: no written informed consent sheet signed or parental approval not obtained, unwillingness to comply with all study procedures
4. Presence or suspicion of any abnormal medical condition which is known or suspected to interfere with anthelminthic treatment
5. Known hypersensitivity to any anthelminthic drugs
6. Recent history of anthelminthic treatment
7. Current or past (within 1 month) participation in any other medical trial
8. For females: suspected or verified pregnancy

### Date of first enrolment
01/11/2008

### Date of final enrolment
31/01/2009

# Locations

### Countries of recruitment
China

Switzerland

**Study participating centre**
**Swiss Tropical Institute**
Basel
Switzerland
CH-4051

# Sponsor information

**Organisation**
Swiss Tropical Institute (STI) (Switzerland)

**Sponsor details**
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Basel
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**Sponsor type**
Research organisation

**Website**
http://www.sti.ch

**ROR**
https://ror.org/03adhka07

# Funder(s)

**Funder type**
Government

**Funder Name**
Stanley Thomas Johnson Foundation (Switzerland)

**Funder Name**

Swiss National Science Foundation (SNSF) (Switzerland) (ref: PBBSP3-123193)

### Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

### 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | 1. results | 01/06/2011 | | Yes | No |