

# Epidemiology and treatment of soil-transmitted helminthiasis, with particular consideration to strongyloidiasis, in Yunnan province, China

<b>Submission date</b> 16/08/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/11/2008	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

### Study objectives

1. Single-dose albendazole and single-dose tribendimidine (both drugs will be administered orally at 200 mg for children aged 5-14 years, and 400 mg for individuals aged  $\geq 15$  years) are safe and efficacious against soil-transmitted helminth infections (*Ascaris lumbricoides*, hookworm and *Trichuris trichuria*)
2. Single-dose tribendimidine has an effect on *Strongyloides stercoralis* and *Taenia* spp

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics Committee of the University and the State of Basel (Ethikkommission beider Basel) (EKBB) Date of approval: 12/06/2007 (ref: 149/07)

### Study design

Open-label, randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Not Specified

## Participant information sheet

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

Helminth infections

### Interventions

The participants who were diagnosed with helminthiasis at the baseline parasitological survey were randomly allocated to the following arms:

Arm 1: Single-dose albendazole (oral), 200 mg for children aged 5-14 years, and 400 mg for individuals aged  $\geq 15$  years

Arm 2: Single-dose tribendimidine (oral), 200 mg for children aged 5-14 years, and 400 mg for individuals aged  $\geq 15$  years

**Intervention Type**

Drug

**Phase**

Not Specified

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

Albendazole, tribendimidine

**Primary outcome measure**

1. Reduction of infection prevalence of intestinal helminths, assessed by examination of stool samples 2-4 weeks after drug administration
2. Frequency and severity of adverse events were recorded within 24 hours after drug administration

**Secondary outcome measures**

Kato-Katz-derived egg count reduction of common soil-transmitted helminths, assessed 2-4 weeks after drug administration.

**Overall study start date**

01/05/2007

**Completion date**

31/07/2007

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

1. Both males and females, age  $\geq 5$  years
2. Submission of  $\geq 1$  stool sample for the baseline parasitological survey
3. For females, not pregnant, as verbally assessed by medical personnel on the day of treatment
4. Absence of major systemic illnesses, as assessed by medical personnel on the day of treatment
5. Written informed consent by the head of the household on behalf of the whole family

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

Approximately 300

**Key exclusion criteria**

1. Presence of any abnormal medical condition, as judged by the medical personnel
2. No stool sample submitted for baseline parasitological survey
3. Enrolled in any other clinical investigation during the study
4. For females: pregnancy

**Date of first enrolment**

01/05/2007

**Date of final enrolment**

31/07/2007

## **Locations**

**Countries of recruitment**

China

Switzerland

**Study participating centre**

Department of Public Health and Epidemiology

Basel

Switzerland

4002

## **Sponsor information**

**Organisation**

Swiss National Science Foundation (SNSF) (Switzerland)

**Sponsor details**

Wildhainweg 3

PO Box 8232

Bern

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info@snf.ch

**Sponsor type**

Government

**Website**

<http://www.snf.ch>

ROR

<https://ror.org/00yjd3n13>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Main funder:

### Funder Name

Commission for Research Partnership with Developing Countries (KFPE) through the Swiss Agency for Development and Cooperation (SDC) (Switzerland)

### Funder Name

Other funders:

### Funder Name

Voluntary Academic Society (Freiwillige Akademische Gesellschaft) (Switzerland)

### Funder Name

Janggen-Pöhn Foundation (Janggen-Pöhn-Stiftung) (Switzerland)

### Funder Name

Chinese Ministry of Science and Technology, through their support to the Key Laboratory of Parasite and Vector Biology of the Chinese Ministry of Health (China) (grant ref: 2005DKA21104)

### Funder Name

Swiss National Science Foundation (Switzerland) (project numbers PPOOB-102883 and PPOOB-119129)

### 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?
<a href="#">Results article</a>	Results	01/08/2008		Yes	No