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

Submission date	Recruitment status
16/08/2008	No longer recruiting
Registration date	**Overall study status**
21/08/2008	Completed
Last Edited	**Condition category**
13/11/2008	Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 >=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 helminthiases 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 >=15 years
Arm 2: Single-dose tribendimidine (oral), 200 mg for children aged 5-14 years, and 400 mg for individuals aged >=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 >=5 years
2. Submission of >=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
Switzerland
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+41 31 308 22 22
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?
Results article	Results	01/08/2008		Yes	No