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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

Contact name
Dr Peter Steinmann

Contact details
Swiss Tropical Institute
Socinstrasse 57
Basel
Switzerland
CH-4051
+41 (0)61 284 8129
peter.steinmann@unibas.ch

Additional identifiers

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)

Primary study design
Interventional

Study design
Community-based, phase IV, open-label/single-blind, randomised controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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)

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, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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