ISRCTN57714676 https://doi.org/10.1186/ISRCTN57714676

Comparing two different doses of praziquantel in Lao school children to treat infections of Schistosoma mekongi and Opisthorchis viverrini

Submission date	Recruitment status	[_] Prospectively registered
12/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/10/2012	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 of praziquantel against Schistosoma mekongi and Opisthorchis viverrini: a randomized, single-blinded dose comparison

Study objectives
A 75 mg dose (per kilogram of body weight) of praziquantel is more efficacious in clearing a Schistosoma mekongi and Opisthorchis viverrini infections than a 40 mg dose (per kilogram of body weight) of praziquantel

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Ethics Committee, Laos (Ref:103/NECHR, 29/01/2007)
Ethics commission of the State of Basel, Switzerland (Ethikkommission beider Basel, EKBB) (Ref: 255/06, amendment of 14/02/2007)

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schistosoma mekongi and Opisthorchis viverrini infections

Interventions
1. Praziquantel 40 mg / kg body weight (1 dose) versus
2. Praziquantel 75 mg / kg body weight (divided into 2 doses of 50 mg/kg + 25 mg/kg, 4 hours apart)

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Schistosoma mekongi and Opisthorchis viverrini infection clearance (no eggs in 3 stool samples examined with Kato-Katz technique) at 28 and 90 days after treatment.

Key secondary outcome(s))
1. Reduction of intensity of infection (reduction of mean number of S. mekongi and O.viverrini eggs per gram of stool sample assessed by Kato-Katz technique) at 28 and 90 days after treatment
2. Diagnostic sensitivity of increasing number of Kato-Katz thick smears before and 28 days after treatment. 'Gold' standard: 9 Kato-Katz thick smears (applied on a sub-sample of the population)

Completion date
31/05/2007

Eligibility

Key inclusion criteria
1. School children (males and females) between 6-16 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Severe illness
3. Non-consent

Date of first enrolment
01/02/2007

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
Lao People's Democratic Republic

Switzerland

Study participating centre

Socinstrasse 57
Basel
Switzerland
4002

Sponsor information

Organisation
Swiss Tropical and Public Health Institute (Switzerland)

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Government

Funder Name
Swiss National Science Foundation and Swiss Agency for Development and Cooperation

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	01/09/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes