

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

Submission date 12/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/10/2012	Condition category 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

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

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

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 measure

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.

Secondary outcome measures

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)

Overall study start date

01/02/2007

Completion date

31/05/2007

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

308 (210 at time of registration)

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

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Sponsor information

Organisation

Swiss Tropical and Public Health Institute (Switzerland)

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Sponsor type

Government

Website

<http://www.swisstph.ch>

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

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	01/09/2012		Yes	No