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

Contact name
Dr Peter Odermatt

Contact details
Socinstrasse 57
Basel
Switzerland
4002
+41 61 284 8214
peter.odermatt@unibas.ch

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
Switzerland
4002

Sponsor information

Organisation
Swiss Tropical and Public Health Institute (Switzerland)

Sponsor details
Socinstrasse 57
Basel
Switzerland
4002
+41 61 284 8111
peter.odermatt@unibas.ch

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