

# Tribendimidine for the treatment of liver fluke infection in Southeast Asia in Laos

<b>Submission date</b> 07/09/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/09/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/01/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Opisthorchiasis and clonorchiasis are parasitic liver fluke infections that are of considerable public health significance in Southeast Asia. There is currently no vaccine available for prevention of liver fluke infections, and hence drug treatment is the current mainstay for clearing infections and subsequently reducing illness. However, treatment of opisthorchiasis relies on a single drug, praziquantel. Efforts are underway to more widely administer praziquantel to prevent infections. There is some concern that this strategy might result in the development and spread of drug-resistant parasites. Against this background, there is a need for new drugs. The aim of this study is to assess the effectiveness and safety of oral tribendimidine, a Chinese anti-parasitic drug, in patients with opisthorchiasis.

### Who can participate?

Patients aged over 8 with opisthorchiasis.

### What does the study involve?

In the first part of the study, participants are assigned to six different groups depending on age. Children aged 8-14 are randomly allocated into three groups, with each group receiving a different dose of tribendimidine. Adults and adolescents aged 15 and above are also randomly allocated into three groups, with each group receiving a different dose of tribendimidine. Blood and stool samples are taken. In the second part of the study, participants are randomly allocated into one of two groups. One group receives the most effective dose of tribendimidine as identified in the first part of the study. The other group is treated with praziquantel in two divided doses. This part of the study is only carried out if the results of the first part of the study are satisfactory. All patients are closely monitored for illness during the period of drug administration. Patients who report adverse events are examined carefully by the study doctor and, when necessary, medical action is taken on the spot or patients are referred to a nearby hospital.

### What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Swiss Tropical and Public Health Institute (Switzerland)

When is the study starting and how long is it expected to run for?

October 2012 to September 2013

Who is funding the study?

Department for International Development (UK), Medical Research Council (UK), Wellcome Trust (UK)

Who is the main contact?

Dr Peter Odermatt

## Contact information

### Type(s)

Scientific

### Contact name

Dr Peter Odermatt

### Contact details

Swiss Tropical and Public Health Institute

Socinstrasse 57

Postfach

4002

Switzerland

4002

## Additional identifiers

## Study information

### Scientific Title

Tribendimidine for the treatment of liver fluke infection in Southeast Asia in Laos

### Acronym

TribOvL

### Study objectives

Current study hypothesis as of 06/02/2017:

1. Tribendimidine dosage for the treatment of *Opisthorchis viverrini* liver fluke is the same as the dosage for the other intestinal parasitic infections
2. Tribendimidine is non inferior than the current standard treatment with praziquantel (non-inferiority margin set at 3%-pts for difference in cure rates)

Previous study hypothesis:

1. Tribendimidine dosage for the treatment of *Opisthorchis viverrini* liver fluke is the same as

the dosage for the other intestinal parasitic infections

2. Tribendimidine has a higher efficacy and fewer adverse events than the current standard treatment with praziquantel

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Ethics Committee of the Canton of Basel and Baselland, 09/02/2012, ref: EKBB 375/11
2. National Ethics Committee Laos, Ministry of Health
3. Liverpool School of Tropical Medicine, Research Ethics Committee, 03/05/2012, ref: 12.02RS

### **Study design**

Randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Liver fluke (*Opisthorchis viverrini*) infection

### **Interventions**

1. Dose finding 2a trial: Children aged 0 to 14 years will be randomized into 3 groups:

Group 1 will receive 50 mg

Group 2 will receive 100 mg

Group 3 200mg tribendimidine.

Patients aged 15 years and above will also be randomized into three treatment groups: group 1 will receive a treatment dose of 100 mg, group 2 200 mg and group 3 400 mg of tribendimidine. Study participants will be randomly assigned to one of these arms using a computerized block randomization procedure.

2. Randomised controlled trial 2b: Most efficacious tribendimidine dosage of trial compared with praziquantel 75mg/kg BW divided in two doses (50 mg/kg BW, 25 mg /kg BW) 4 hours apart

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Tribendimidine, praziquantel

### **Primary outcome(s)**

*O. viverrini* infection: cure rates and egg reduction rates

### **Key secondary outcome(s)**

1. Adverse events observed with tribendimidine and praziquantel
2. PK parameters of tribendimidine in patients infected with *O. viverrini*
3. Co-infection with soil-transmitted helminths (hookworm, *A. lumbricoides*, *T. trichiura*)

**Completion date**

30/09/2013

## Eligibility

**Key inclusion criteria**

1. Patients (older than 8 years) infected with *O. viverrini* (respectively: *C. sinensis* in PR China), as assessed by the presence of eggs in the stool
2. Able and willing to be examined by a study physician at the beginning of the study and at the end-of study (3 weeks post-treatment)
3. Able and willing to provide 2 stool samples at the beginning and end of study
4. Absence of major systemic illnesses, as assessed by the medical doctor, upon initial clinical assessment
5. Absence of psychiatric and neurological disorders
6. No known or reported hypersensitivity to tribendimidine
7. No known or reported history of chronic illness as cancer, diabetes, chronic heart, liver or renal disease
8. Signed written informed consent sheet
9. For females aged 12 years and above, not pregnant, as assessed by a female nurse (interview and pregnancy test), upon initial clinical assessment

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. Pregnancy
2. Presence of any abnormal medical condition, judged by the study physician.
3. Concurrent non-helminthic infectious disease as judged by the study clinician (for malaria, use rapid diagnostic test to diagnose).
4. History of acute or severe chronic disease
5. Known or reported psychiatric or neurological disorders
6. Use of praziquantel and other helminth treatment within the past three months
7. Attending other clinical trials during the study

**Date of first enrolment**

01/10/2012

**Date of final enrolment**

30/09/2013

## Locations

**Countries of recruitment**

Lao People's Democratic Republic

Switzerland

**Study participating centre**

Swiss Tropical and Public Health Institute

4002

Switzerland

4002

## Sponsor information

**Organisation**

Swiss Tropical and Public Health Institute (Switzerland)

**ROR**

<https://ror.org/03adhka07>

## Funder(s)

**Funder type**

Government

**Funder Name**

Department for International Development

**Alternative Name(s)**

Department for International Development, UK, DFID

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Medical Research Council (ref: G1100699)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Wellcome Trust (ref: 096471)

**Alternative Name(s)**

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

International organizations

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	01/10/2016		Yes	No
	results				

[Results article](#)

01/02/2018

Yes

No