

# Mefloquine, artesunate, mefloquine-artesunate and tribendimidine against opisthorchiasis

<b>Submission date</b> 15/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/03/2011	<b>Condition category</b> 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

**Contact name**  
Prof Jennifer Keiser

**Contact details**  
Department of Medical Parasitology and Infection Biology  
Swiss Tropical and Public Health Institute  
Socinstr. 57  
Basel  
Switzerland  
4051

## Additional identifiers

## Study information

**Scientific Title**  
Mefloquine, artesunate, mefloquine-artesunate and tribendimidine in the treatment of *Opisthorchis viverrini* infection in Laos

**Acronym**  
MQAS-Opi

**Study objectives**

Mefloquine and artesunate, administered singly or in combination, and tribendimidine show efficacy against *Opisthorchis viverrini* in school-aged children in Africa

### **Ethics approval required**

Old ethics approval format

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

1. Ethics commission of Basel (Ethikkommission beider Basel [EKBB]), Switzerland approved on the 23rd July 2009 (ref: 209/09)
2. Ministry of Health Lao PDR approved on the 3rd February 2010 (ref: 25/2010)

### **Study design**

Phase 2 randomised exploratory open label active controlled parallel group trial

### **Primary study design**

Interventional

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

Treatment

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

Infection with *Opisthorchis viverrini*

### **Interventions**

Drug administration, namely

1. Mefloquine (1x 25 mg/kg)
2. Artesunate (10 mg/kg in three divided doses within 1 day)
3. Mefloquine-artesunate combination (300/750 mg in three divided doses within 3 days)
4. Praziquantel (3x 25 mg/kg within 1 day)
5. Tribendimidine (1 x 200 mg (below age of 14) or 400 mg (above age of 14))

The duration of treatment is 1-3 days, depending on the drug. Duration of follow up is 3-5 days.

### **Intervention Type**

Drug

### **Phase**

Phase II

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

Artesunate, mefloquine, praziquantel, tribendimidine

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

Cure rate and egg reduction rate

21-28 Days post treatment by multiple stool sampling (Kato Katz method, Ether concentration technique and PCR)

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

Adverse events

Patients will be monitored for 3 hours post treatment and once daily for 5 days. Details of adverse events will be recorded by the study physician during the trial including variables

describing their incidence, onset, cessation, duration, intensity, frequency, seriousness, and causality.

**Completion date**

01/05/2010

**Eligibility**

**Key inclusion criteria**

1. Patients (male and female schoolchildren older than 8 years) infected with *O. viverrini*, as assessed by the presence of eggs in the stool
2. Weight of patient greater than 25 kg
3. 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)
4. Able and willing to provide multiple stool samples at the beginning and end of study
5. Absence of major systemic illnesses, as assessed by the medical doctor, upon initial clinical assessment
6. Absence of psychiatric and neurological disorders
7. No known or reported hypersensitivity to mefloquine, tribendimidine and/or artesunate
8. No known or reported history of chronic illness as cancer, diabetes, chronic heart, liver or renal disease
9. Signed written informed consent sheet
10. For females aged 12 years and above, not pregnant in the first trimester, as assessed by a pregnancy test, upon initial clinical assessment

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Key exclusion criteria**

1. Pregnancy first trimester
2. Presence of any abnormal medical condition, judged by the study physician
3. History of acute or severe chronic disease
4. Known or reported psychiatric or neurological disorders
5. Use of artesunate, artemether, any ACT, mefloquine or praziquantel within the past month
6. Attending other clinical trials during the study

**Date of first enrolment**

01/03/2010

**Date of final enrolment**

01/05/2010

# Locations

## Countries of recruitment

Lao People's Democratic Republic

Switzerland

## Study participating centre

Department of Medical Parasitology and Infection Biology

Basel

Switzerland

4051

# Sponsor information

## Organisation

Swiss Tropical and Public Health Institute (Switzerland)

## ROR

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

# Funder(s)

## Funder type

University/education

## Funder Name

University of Basel (Switzerland)

# 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				

[Results article](#)

01/02/2011

Yes

No