

# Tribendimidine in the treatment of liver fluke infection in China

<b>Submission date</b> 07/03/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/03/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/08/2013	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Clonorchiasis, a disease caused by the oriental liver fluke *Clonorchis sinensis*, is of considerable public health importance. The disease is constantly present in the Peoples Republic of China, Taiwan, Vietnam, and the Republic of Korea, where an estimated 601 million people are at risk and more than 35 million people are infected. There is currently no vaccine available for prevention of clonorchiasis and chemotherapy is the main treatment. However, chemotherapy of clonorchiasis relies on a single drug called praziquantel. Efforts are underway to administer praziquantel more widely, in preventive chemotherapy campaigns. There is some concern that this strategy might result in the development and spread of drug-resistant parasites. There is a need for discovery and development of new drugs. The aim of this study is to assess how well oral tribendimidine works in patients infected with *C. sinensis*.

### Who can participate?

75 individuals with a parasitological-confirmed infection with *C. sinensis*

### What does the study involve?

Patients will be randomly allocated to one of three groups:

- single oral dose of 400 mg tribendimidine
- oral doses of 400 mg tribendimidine daily for 3 days
- praziquantel (25 mg/kg 3 times a day) for 2 consecutive days

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

The two drugs which are compared are well known, widely used and have little adverse events. All children enrolled in the study will benefit from a treatment against liver fluke infection and soil transmitted helminths. All diagnosed parasitic infections will be treated according to national guidelines.

### Where is the study run from?

Guangdong province, China.

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

The study will last for 5-6 weeks and will take place in March/April 2012.

Who is funding the study?  
The study will be funded by DFID/Wellcome Trust/MRC.

Who is the main contact?  
Professor Jennifer Keiser

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Jennifer Keiser

**Contact details**  
Socinstr. 57  
Basel  
Switzerland  
4051

## Additional identifiers

## Study information

**Scientific Title**  
Tribendimidine in the treatment of Clonorchis sinensis infection in the Peoples Republic of China

**Study objectives**  
Tribendimidine achieves a higher efficacy than praziquantel in the treatment of Clonorchis infections

Follow up to <http://www.controlled-trials.com/ISRCTN23425032>

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethikkommission Beider, Basel, 09 February 2012 ref: 375/11

**Study design**  
Randomized exploratory open-label phase II trial with three treatment arms

**Primary study design**  
Interventional

**Study type(s)**  
Treatment

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

Liver fluke infections (*Clonorchis sinensis*)

### **Interventions**

Group 1: single oral dose of 400 mg tribendimidine

Group 2: oral doses of 400 mg tribendimidine daily for 3 days

Group 3: praziquantel (25 mg/kg 3 times a day) for 2 consecutive days

Follow up is 21 days after treatment. Praziquantel brand names are Biltricide® and Cesol®.

### **Intervention Type**

Drug

### **Phase**

Phase II

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

Praziquantel, tribendimidine

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

Cure rates and egg reduction rates three weeks after treatment:

For diagnosis three stool samples will be collected before and after treatment. From each stool sample three Kato-Katz thick smears will be examined. Additionally 1g of stool will be preserved for later diagnosis with the ether concentration method.

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

Adverse events due to specific treatment:

Participants will be monitored 3 hours after treatment. 24 hours after each day of treatment they will be asked with a standard questionnaire for adverse events.

### **Completion date**

10/05/2012

## **Eligibility**

### **Key inclusion criteria**

1. Patients (adults aged  $\geq 18$  years) infected with *C. sinensis*, as assessed by the presence of eggs in the stool
2. Signed written informed consent
3. Able and willing to be examined by a study physician at the beginning of the study and at the end-of study follow-up survey (3 - 4 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, psychiatric and neurological disorders as assessed by the medical doctor, upon initial clinical assessment
6. No known or reported hypersensitivity to tribendimidine or praziquantel
7. No known or reported history of chronic illness as cancer, diabetes, chronic heart, liver or renal disease
8. For females, not pregnant in the first trimester, as assessed by a female nurse (interview and pregnancy test if need be), upon initial clinical assessment

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. For females, pregnancy in 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 hypersensitivity to tribendimidine or praziquantel
5. Known or reported psychiatric or neurological disorders
6. Use of any anthelmintic within the past month
7. Attending other clinical trials during the study
8. Absence of signed written informed consent sheet

**Date of first enrolment**

10/03/2012

**Date of final enrolment**

10/05/2012

**Locations**

**Countries of recruitment**

China

Switzerland

**Study participating centre**

**Socinstr. 57**

Basel

Switzerland

4051

**Sponsor information**

**Organisation**

Medical Research Council (UK)

**ROR**

<https://ror.org/03x94j517>

**Funder(s)****Funder type**

Government

**Funder Name**

Department For International Development [DFID] (UK)

**Funder Name**

Medical Research Council (MRC) (UK)

**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 (UK) ref: G1100699

**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	01/04/2013		Yes	No