

# Study of treatment of patients with *Opisthorchis felinus* infection

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/08/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/09/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

*Opisthorchis felinus* is a parasitic worm that causes opisthorchiasis (liver infection). It is mainly found in the Ob-Irtish river basin running from the south to north of Western Siberia (Russia). The prevalence of opisthorchiasis in Siberian people is estimated to be up to 50–80%. An infection can cause abdominal pain, jaundice, weakness, loss of appetite, diarrhea, itching and skin rash. The only drug officially registered in Russia for the treatment of opisthorchiasis is praziquantel. The aim of this study is to compare the effectiveness and safety of different praziquantel treatments against *Opisthorchis felinus* infection.

### Who can participate?

Patients aged between 18 and 65 who have *Opisthorchis felinus* infection

### What does the study involve?

Participants are randomly allocated to one of five groups. Those in the first group receive 20 mg/kg body weight (BW) of praziquantel in a single oral daily dose. Those in the second group receive 40 mg/kg BW of praziquantel in a single oral daily dose. Those in the third group receive 60 mg/kg BW of praziquantel in a single oral daily dose. Those in the fourth group receive 60 mg/kg BW divided into three intakes per day (the standard treatment in Russia). Those in the fifth group receive a single dose of a placebo (dummy drug). 18–25 days after receiving the treatment, participants provide two stool samples on two different days which are tested for signs of parasitic worm eggs. Participants are also interviewed before treatment and within the follow-up period about whether they have experienced any side effects.

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

All participants benefit from receiving a clinical examination and *Opisthorchis felinus* infection treatment. All participating patients from the placebo group who are positive for *Opisthorchis felinus* infection at the end of the study are treated with standard treatment with praziquantel. There are no notable risks involved with participating.

### Where is the study run from?

Siberian State Medical University (Russian Federation)

When is the study starting and how long is it expected to run for?  
June 2017 to March 2018

Who is funding the study?  
Russian Foundation for Basic Research (Russian Federation)

Who is the main contact?  
1. Prof. Jennifer Keiser (Coordinator from Swiss TPH)  
jennifer.keiser@unibas.ch  
2. Prof. Olga Fedorova (Coordinator from SSMU)  
olga.sergeevna.fedorova@gmail.com  
3. Prof. Tatiana Ageeva (Principal Investigator at SSMU)  
ts.ageeva@mail.ru

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Olga Fedorova

**ORCID ID**  
<https://orcid.org/0000-0002-7130-9609>

**Contact details**  
Moscowsky tract, 2  
Tomsk  
Russian Federation  
634050  
+7 (3822)901101, add 1733  
olga.sergeevna.fedorova@gmail.com

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
v 01 (10.05.2017)

## Study information

**Scientific Title**  
Dose-finding and pharmacokinetic studies of praziquantel in patients infected with *Opisthorchis felineus*

**Study objectives**

The purpose of this study is to assess the safety and efficacy of different praziquantel short course treatment schemes against *Opisthorchis felinus* infection.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of Siberian State Medical University, 29/05/2017, ref: N 5308

**Study design**

Randomized controlled single-blind study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

*Opisthorchis felinus* infection

**Interventions**

Patients will be randomized using block randomization to one of five groups:

Intervention group 1: Participants receive praziquantel 20 mg/kg BW (body weight) by single oral daily dose

Intervention group 2: Participants receive praziquantel 40 mg/kg BW by single oral daily dose

Intervention group 3: Participants receive praziquantel 60 mg/kg BW by single oral daily dose

Intervention group 4: Participants receive praziquantel 60 mg/kg BW divided into three intakes per day (standard treatment in Russia)

Control group 5: Participants receive a single dose of a placebo

The duration of the treatment is one day (for interventional groups 1, 2, 3, 5 - single dose, for interventional group 4 - multiple dose). The duration of the follow-up is 18-25 days. 18-25 days after receiving the treatment, participants provide two stool samples (in two different days) which are then tested for signs of parasitic worm eggs. Participants are also interviewed before treatment and within the follow-up period about whether they have experienced any side effects. The pharmacokinetics assessment is performed within 24 hours after intake of the praziquantel.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Praziquantel

**Primary outcome(s)**

Cure rate (i.e. conversion from being *Opisthorchis felinus* egg positive pre-treatment to egg negative post-treatment) on 18-25 days of the follow-up. The parasitological study will be used for the confirmation of the *Opisthorchis felinus* infection (microscopy of stool, quantitative analysis with PARASEP technique). For the post-treatment point two stool samples on two different days will be collected and analysed

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

1. Egg reduction rate against *Opisthorchis felinus* infection assessed post-treatment assessed pre-treatment to post-treatment on 18-25 days of the follow-up. The parasitological study will be used for the assessment of the intensity of *Opisthorchis felinus* infection (microscopy of stool, qualitative analysis with PARASEP technique). For the post-treatment point two stool samples on two different days will be collected and analysed
2. Pharmacokinetic parameters: drug concentrations measured at 0, 0.5, 1, 1.5, 2, 2.5, 3, 6, 8, 12, 24 hours (single doses) and 0, 1, 2, 4, 5, 6, 7, 8, 10, 12, 24 hours (multiple doses) post-dosing

### **Completion date**

01/03/2018

## **Eligibility**

### **Key inclusion criteria**

1. Written informed consent signed by participant prior to any study procedures
2. Patients 18-65 years and infected with *Opisthorchis felinus* as assessed by the presence of eggs in the stool
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 2 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 praziquantel
8. No known or reported history of chronic illness as cancer, diabetes, chronic heart, liver or renal disease

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

110

**Key exclusion criteria**

1. No written informed consent
2. Presence of any abnormal medical condition, judged by the study physician
3. History of acute or severe chronic disease such as liver or renal disease
4. Recent use of anthelmintic drug (within past 4 weeks)
5. Pregnancy or breastfeeding
6. History of acute or severe chronic disease
7. Known or reported psychiatric or neurological disorders
8. Administration of any investigational product or use of any investigational device within 30 days prior to praziquantel administration
9. Subjects who have used drugs that may affect the pharmacokinetics of praziquantel from 15 days before dosing until the last PK sample, e.g., phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate, rifampicin, nelfinavir, ritonavir, griseofulvin, oral ketoconazole
10. Consumption of substances known to be potent inhibitors or inducers of CYP P450s such as grapefruit juice, grapefruit juice containing products, and herbal remedies or dietary supplements containing St. John's Wort, in the two weeks before dosing
11. Attending other clinical trials during the study
12. Negative diagnostic result for *Opisthorchis felineus*
13. Allergy to praziquantel

**Date of first enrolment**

01/06/2017

**Date of final enrolment**

15/02/2018

**Locations****Countries of recruitment**

Russian Federation

**Study participating centre**

**Siberian State Medical University**

Moscowsky trakt, 2

Tomsk

Russian Federation

634050

**Sponsor information**

## Organisation

Siberian State Medical University

## ROR

<https://ror.org/01yecu831>

## Funder(s)

### Funder type

Government

### Funder Name

Russian Foundation for Basic Research

### Alternative Name(s)

Российский Фонд Фундаментальных Исследований, Russian Foundation for Basic Research (Russia), RFBR, РФФИ

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Russian Federation

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Olga Fedorova ([olga.sergeevna.fedorova@gmail.com](mailto:olga.sergeevna.fedorova@gmail.com)). The data will be available from mid 2019 onwards, and access will be decided on a case by case basis. Only analyses mentioned in the protocol and ICF will be allowed and data will be anonymized.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	PK and dose-finding results	18/10/2022	20/09/2023	Yes	No