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# Study of treatment of patients with Opisthorchis felineus infection

**Submission date**
17/07/2017

**Recruitment status**
No longer recruiting

**Registration date**
09/08/2017

**Overall study status**
Completed

**Last Edited**
20/09/2023

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Opisthorchis felineus is a parasitic worm that causes opisthorchiasis (liver infection). It is mainly found in the Ob-Irtisch 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 felineus infection.

Who can participate?
Patients aged between 18 and 65 who have Opisthorchis felineus 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 felineus infection treatment. All participating patients from the placebo group who are positive for Opisthorchis felineus 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)
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2. Prof. Olga Fedorova (Coordinator from SSMU)
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3. Prof. Tatiana Ageeva (Principal Investigator at SSMU)
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Olga Fedorova

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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 felineus 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

## 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 to request a patient information sheet

## Health condition(s) or problem(s) studied
Opisthorchis felineus 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

### Pharmaceutical study type(s)
Pharmacokinetic, Dose response

### Phase
Not Applicable

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

### Primary outcome measure
Cure rate (i.e. conversion from being Opisthorchis felineus 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 felineus 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

### Secondary outcome measures
1. Egg reduction rate against Opisthorchis felineus 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 felineus 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

### Overall study start date
01/06/2017

### 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 felineus 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

## Age group
Adult

## Lower age limit
18 Years

## Upper age limit
65 Years

## Sex
Both

## Target number of participants
200

## 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 anthelminthic 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, carbamazapine, 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

**Sponsor details**
Moscowskiy trakt, 2
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634050

**Sponsor type**
University/education

**ROR**
https://ror.org/01yecy831

# 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

### Publication and dissemination plan
Planned scientific publication in a peer-reviewed journal.

### Intention to publish date
31/12/2018

### 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). 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? |
|---|---|---|---|---|---|
| Results article | PK and dose-finding results | 18/10/2022 | 20/09/2023 | Yes | No |