

Dose-finding and pharmacokinetic studies of praziquantel in patients infected with *Opisthorchis viverrini*

Submission date 22/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Opisthorchiasis is a neglected tropical disease caused by liver flukes (parasites) for which only a single drug is available, praziquantel. Praziquantel doses used for the treatment are still experimental and the nature of the drug has not yet been studied. We aim to compare the effectiveness and safety of four oral praziquantel doses in patients infected with *Opisthorchis viverrini* and to measure praziquantel disposition using dried blood spot technology.

Who can participate?

Adult men and women infected with *O. viverrini* can participate in the study.

What does the study involve?

Three stool samples will be collected on different days within a maximum of 5 days. Medical history of patients participating in the study will be assessed with a standardized and previously used questionnaire, in addition to a full clinical examination carried out by the study doctor. Participants will be randomly allocated to one of the four praziquantel doses or to receive a placebo (dummy). Praziquantel will be given based on weight. A small amount of blood will be collected by pricking the tip of the middle or ring finger. Blood will be collected at different time points after dosing. A few drops of blood will be transferred at each time point onto filter paper and dried for about 1 hour. The dried blood spot cards will be transported to Basel, Switzerland and stored at -20° C until they are analysed. Side effects will be carefully studied up to 72 hours after treatment by experienced doctors. The effectiveness of the treatment will be determined 19-25 days after treatment by collecting another three stool samples, collected on consecutive days, and microscopically examining the samples for eggs. Patients will be considered *Opisthorchis* negative if no eggs have been found in the stool or specimens.

What are the possible benefits and risks of participating?

This study will increase our understanding of the nature of the drug praziquantel. All procedures in this study are routinely conducted at a health facility. They do not bear any particular additional risks. Side effects are mild and include stomach pain and dizziness.

Where is the study run from?

The study will take in a village in remote Laos (single study site).

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

The study starts in August 2014 and runs until December 2014.

Who is funding the study?

Swiss National Science Foundation, Switzerland.

Who is the main contact?

Prof Jennifer Keiser

jennifer.keiser@unibas.ch

Contact information

Type(s)

Scientific

Contact name

Prof Jennifer Keiser

Contact details

Socinstr. 57

PO Box

Basel

Switzerland

4051

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Dose-finding and pharmacokinetic studies of praziquantel in patients infected with *Opisthorchis viverrini*: a randomized, controlled phase 2 single-blind dose-finding trial

Acronym

Opipraz

Study objectives

The currently used praziquantel dosages are empirical and could be improved through dose-finding and pharmacokinetic studies.

Ethics approval required

Old ethics approval format

Ethics approval(s)

EKNZ 2014-163 and ethical clearance Lao PDR

Study design

Randomized, controlled phase 2 single-blind dose-finding trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Opisthorchiasis

Interventions

Participants will be randomized to one of four treatment groups or a control group (given a placebo)

1. Praziquantel 30 mg/kg
2. Praziquantel 40 mg/kg
3. Praziquantel 50 mg/kg
4. Praziquantel 3 x 25 mg/kg

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Praziquantel

Primary outcome measure

Cure rate: measured 21 days post-treatment

Secondary outcome measures

1. Egg reduction rate: measured 21 days post-treatment
2. Pharmacokinetic parameters: measured up to 24 hours post-treatment
3. Safety: measured 3 hours and 24 hours post-treatment

Overall study start date

15/08/2014

Completion date

01/12/2014

Eligibility

Key inclusion criteria

1. Written informed consent signed by participant
2. Age 15-65 years
3. Able and willing to be examined by a study physician at the beginning of the study and 3 weeks after treatment
4. Able and willing to provide three stool samples at the beginning of the study and 3 weeks after treatment
5. Able and willing to provide 11 finger prick blood samples for PK studies
6. Infected with *O. viverrini*
7. Absence of major systemic illnesses as assessed by a medical doctor, upon initial clinical assessment
8. No known allergy to study medications

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

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. Administration of any investigational product or use of any investigational device within 30 days prior to praziquantel administration. 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

7. 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 Johns Wort, in the two weeks before dosing

8. Attending other clinical trials during the study

9. Below 15 years of age

10. Negative diagnostic result for Opisthorchis

11. Allergy to praziquantel

Date of first enrolment

15/08/2014

Date of final enrolment

01/12/2014

Locations

Countries of recruitment

Lao People's Democratic Republic

Switzerland

Study participating centre

Socinstr. 57

Basel

Switzerland

4051

Sponsor information

Organisation

Swiss Tropical and Public Health Institute (Switzerland)

Sponsor details

c/o Jennifer Keiser

Socinstr. 57

PO Box

Basel

Switzerland

4051

Sponsor type

Research organisation

ROR

Funder(s)

Funder type

Research organisation

Funder Name

Swiss National Science Foundation (Switzerland)

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Basic results		22/01/2019	22/01/2019	No	No