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

Submission date
22/07/2014

Recruitment status
No longer recruiting

Registration date
27/08/2014

Overall study status
Completed

Last Edited
22/01/2019

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
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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Cure rate: measured 21 days post-treatment

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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. 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 thepharmacokinetics 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
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)

ROR
https://ror.org/03adhka07

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, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		22/01/2019	22/01/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes