

Mefloquine, artesunate, mefloquine-artesunate and tribendimidine against opisthorchiasis

Submission date 15/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/03/2011	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Mefloquine, artesunate, mefloquine-artesunate and tribendimidine in the treatment of *Opisthorchis viverrini* infection in Laos

Acronym

MQAS-Opi

Study objectives

Mefloquine and artesunate, administered singly or in combination, and tribendimidine show efficacy against *Opisthorchis viverrini* in school-aged children in Africa

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics commission of Basel (Ethikkommission beider Basel [EKBB]), Switzerland approved on the 23rd July 2009 (ref: 209/09)
2. Ministry of Health Lao PDR approved on the 3rd February 2010 (ref: 25/2010)

Study design

Phase 2 randomised exploratory open label active controlled parallel group 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

Infection with *Opisthorchis viverrini*

Interventions

Drug administration, namely

1. Mefloquine (1x 25 mg/kg)
2. Artesunate (10 mg/kg in three divided doses within 1 day)
3. Mefloquine-artesunate combination (300/750 mg in three divided doses within 3 days)
4. Praziquantel (3x 25 mg/kg within 1 day)
5. Tribendimidine (1 x 200 mg (below age of 14) or 400 mg (above age of 14))

The duration of treatment is 1-3 days, depending on the drug. Duration of follow up is 3-5 days.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Artesunate, mefloquine, praziquantel, tribendimidine

Primary outcome measure

Cure rate and egg reduction rate

21-28 Days post treatment by multiple stool sampling (Kato Katz method, Ether concentration technique and PCR)

Secondary outcome measures

Adverse events

Patients will be monitored for 3 hours post treatment and once daily for 5 days. Details of adverse events will be recorded by the study physician during the trial including variables describing their incidence, onset, cessation, duration, intensity, frequency, seriousness, and causality.

Overall study start date

01/03/2010

Completion date

01/05/2010

Eligibility**Key inclusion criteria**

1. Patients (male and female schoolchildren older than 8 years) infected with *O. viverrini*, as assessed by the presence of eggs in the stool
2. Weight of patient greater than 25 kg
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 multiple 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 mefloquine, tribendimidine and/or artesunate
8. No known or reported history of chronic illness as cancer, diabetes, chronic heart, liver or renal disease
9. Signed written informed consent sheet
10. For females aged 12 years and above, not pregnant in the first trimester, as assessed by a pregnancy test, upon initial clinical assessment

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Pregnancy 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 psychiatric or neurological disorders
5. Use of artesunate, artemether, any ACT, mefloquine or praziquantel within the past month
6. Attending other clinical trials during the study

Date of first enrolment

01/03/2010

Date of final enrolment

01/05/2010

Locations

Countries of recruitment

Lao People's Democratic Republic

Switzerland

Study participating centre

Department of Medical Parasitology and Infection Biology

Basel

Switzerland

4051

Sponsor information

Organisation

Swiss Tropical and Public Health Institute (Switzerland)

Sponsor details

Socinstr. 57

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Basel
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Sponsor type

Research organisation

ROR

<https://ror.org/03adhka07>

Funder(s)

Funder type

University/education

Funder Name

University of Basel (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?
Results article	results	01/02/2011		Yes	No