ISRCTN23425032 https://doi.org/10.1186/ISRCTN23425032

Mefloquine, artesunate, mefloquine-artesunate and tribendimidine against opisthorchiasis

Submission date
15/02/2010

Recruitment status
No longer recruiting

Registration date
16/03/2010

Overall study status
Completed

Last Edited
16/03/2011

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jennifer Keiser

Contact details
Department of Medical Parasitology and Infection Biology
Swiss Tropical and Public Health Institute
Socinstr. 57
Basel
Switzerland
4051

Additional identifiers

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 (Ethikkomission 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)

Primary study design
Interventional

Study design
Phase 2 randomised exploratory open label active controlled parallel group trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Sex
All

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 Insitute (Switzerland)

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
University/education

Funder Name
University of Basel (Switzerland)

Results and Publications

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				

Results article	01/02/2011	Yes	No