

Mefloquine and artesunate against schistosomiasis

Submission date 15/10/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 17/10/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/06/2010	Condition category Infections and Infestations	☐ 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

Study information

Scientific Title
Mefloquine, artesunate and mefloquine-artesunate in the treatment of *Schistosoma mansoni* and *Schistosoma haematobium* infections in Côte d'Ivoire

Acronym
MQAS-Schisto

Study objectives

Mefloquine and artesunate, administered singly or in combination, show efficacy against *Schistosoma mansoni* and *Schistosoma haematobium* in school-aged children in Africa.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethikkommission beider Basel EKBB (Switzerland) on the 7th April 2008 (ref: 70/08)
2. Ministère de la Santé d'Hygiène et Publique (Cote d'Ivoire) on the 20th June 2008 (ref: 2868 /MSHP)

Primary study design

Interventional

Study design

Open-label randomised trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schistosomiasis (*Schistosoma mansoni*; *Schistosoma haematobium*)

Interventions

1. Mefloquine (1 x 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 (1 x 40 mg/kg)

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mefloquine, artesunate, praziquantel

Primary outcome(s)

Cure rate and egg reduction rate, measured 21 - 28 days post-treatment by multiple stool sampling using the Kato-Katz method (study 1) and multiple urine sampling using standard urine filtration method (study 2).

Key secondary outcome(s)

Patients will be monitored for three 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

20/10/2009

Eligibility

Key inclusion criteria

1. Schoolchild (aged 8 - 16 years, either sex) infected with *S. mansoni* (study 1) or *S. haematobium* (study 2), as assessed by the presence of egg(s) in the stool (*S. mansoni*) or urine (*S. haematobium*)
2. Weight of schoolchild greater than 25 kg
3. Able and willing to be examined by a 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 or urine 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 disorders and epilepsy
7. No known or reported hypersensitivity to mefloquine 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 by parents/legal guardians and child
10. For females aged 12 years and above, not pregnant in the first trimester, as assessed by a female nurse (interview and pregnancy test if need be), upon initial clinical assessment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 Years

Upper age limit

16 Years

Sex

All

Key exclusion criteria

1. Schoolchild who has clinical malaria (i.e. axillary temperature greater than or equal to 37.5°C and parasitaemia, as assessed by thick and thin blood film examination)

2. Pregnancy first trimester
3. Presence of any abnormal medical condition, judged by the study physician
4. History of acute or severe chronic disease, including hepato-splenic schistosomiasis, macrohaematuria and bloody stools
5. Psychiatric disorders and epilepsy
6. Use of artesunate, artemether, any artemisinin-based combination therapy, mefloquine or praziquantel within the past 7 days
7. Attending other clinical trials during the study

Date of first enrolment

30/10/2008

Date of final enrolment

20/10/2009

Locations

Countries of recruitment

Côte d'Ivoire

Switzerland

Study participating centre

Department of Medical Parasitology and Infection Biology

Basel

Switzerland

4002

Sponsor information

Organisation

Swiss Tropical Institute (Switzerland)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

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 article	results	01/05/2010		Yes	No