

Praziquantel, praziquantel plus mefloquine and praziquantel plus mefloquine-artesunate in the treatment of schistosomiasis

Submission date 06/05/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 27/05/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2015	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
Praziquantel, praziquantel plus mefloquine and praziquantel plus mefloquine-artesunate in the treatment of infections with *Schistosoma* spp. in Cote d'Ivoire

Acronym
PZQM-Schisto

Study objectives

Combinations of mefloquine and mefloquine-artesunate plus praziquantel show a better efficacy against *Schistosoma* spp. infections in school-aged children in Africa.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethikkommission beider Basel EKBB, Switzerland, 21/08/2009, ref: 70/08
2. Ministry of Health Cote d'Ivoire, 03/04/2010

Primary study design

Interventional

Study design

Randomised exploratory open-label active-controlled parallel-group phase II trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Infection with *Schistosoma* spp.

Interventions

Drug administration, namely:

1. Praziquantel (1 x 40 mg/kg)
2. Mefloquine (1 x 25 mg/kg) plus praziquantel (1 x 40 mg/kg) on the next day
3. Mefloquine-artesunate combination (300/750 mg in three divided doses within 3 days) plus praziquantel (1 x 40 mg/kg) on day 4

The duration of treatment is dependant on the drug regimen (i.e., 1 - 4 days). The total duration of follow-up is 3 - 5 days.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Praziquantel, mefloquine, mefloquine-artesunate

Primary outcome(s)

Cure rate and egg reduction rate, measured at 21 - 28 days and 2 - 3 months post-treatment by multiple stool and urine sampling (Kato Katz method, urine filtration and ether concentration technique)

Key secondary outcome(s)

Adverse events. Patients will be monitored for 3 hours post-treatment and once daily during treatment and for 3 days after the last dose. 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

30/09/2011

Eligibility

Key inclusion criteria

1. Patients (male and female school children older than 8 years) infected with *Schistosoma mansoni* and *S. haematobium*, as assessed by the presence of eggs in the urine or 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 and 2 - 3 months post-treatment)
4. Able and willing to provide multiple stool and 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 and neurological disorders
7. No known or reported hypersensitivity to mefloquine, praziquantel 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

Lower age limit

8 Years

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 antimalarial or anthelmintic drug within the past month
6. Attending other clinical trials during the study

Date of first enrolment

01/07/2011

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

Côte d'Ivoire

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 (Fonds National Suisse de la Recherche Scientifique [SNSF]) (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?
Results article	results	17/07/2014		Yes	No