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

Submission date	Recruitment status	[X] Prospectively registered
06/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jennifer Keiser

Contact details
Socinstr. 57
Basel
Switzerland
4051

Additional identifiers

Protocol serial number
N/A

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

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

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

Primary study design
Interventional

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 recorded by the study physician during the trial, including variables describing their incidence, onset, cessaton, duration, intensity, frequency, seriousnes 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 chronical 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 anthelminthic 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