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Mefloquine and artesunate against schistosomiasis

Submission date	Recruitment status	[X] Prospectively registered
15/10/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/06/2010	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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 and mefloquine-artesunate in the treatment of Schistosoma mansoni and Schistosoma haematobium infections in Côte dIvoire

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

Study design
Open-label randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
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 measure
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).

Secondary outcome measures
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.

Overall study start date
30/10/2008

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 chronical illness as cancer, diabetes, chronic heart, liver or renal disease
9. Signed written informed consent sheet by parents/legual 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

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Total: 120 (study 1: 60; study 2: 60)

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
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Sponsor information

Organisation
Swiss Tropical Institute (Switzerland)

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Sponsor type
Research organisation

Website
http://sti.ch

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Industry

Funder Name
Mepha Pharma AG (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	01/05/2010		Yes	No