

Assessment of the safety and efficacy of different drugs and drug combinations in children infected with schistosomes

Submission date 27/04/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 19/07/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/08/2023	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Schistosomiasis is an infection caused by parasites that live in fresh water in subtropical and tropical regions of the world. There are six species of schistosomes; *S. mansoni*, *S. japonicum* and *S. haematobium* are the most common. Each year around 230 million people are infected with schistosomes, and around 11,000 people die from the infection. Schistosomiasis can become a persistent chronic disorder in areas with high infection rates, which results in common disabling complications such as anaemia, stunted growth, slow mental development and decreased fitness. The aim of this study is to test how well 4 different drugs work to cure the infection and reduce the number of schistosomes eggs in an infected person's body. We will be testing how well moxidectin, Synriam® and a Synriam®-praziquantel combination work against schistosome infections compared to taking praziquantel alone. This study will also be testing how safe the drugs are for school children, how effective moxidectin, Synriam® and Synriam®/praziquantel combination are against possible co-infections (*Ascaris lumbricoides*, *Trichuris trichiura*, hookworm, *Strongyloides stercoralis*) and how effective Synriam® is against malaria infection.

Who can participate?

Children infected with schistosomes.

What does the study involve?

Participants are randomly allocated into one of four groups. Those in group 1 (intervention group) are given the drug moxidectin. Those in group 2 (intervention group) are given the drug Synriam®. Those in group 3 (intervention group) are given the drug combination Synriam® and praziquantel. Those in group 4 (intervention group) are given the drug praziquantel. Participants are asked to give urine and stool samples, and a finger prick blood test at the start of the study, then again 3 and 6 weeks after treatment. The medical history of participants is assessed using a questionnaire, and a clinical examination is carried out by the study physician on the day of treatment. There are interviews before treatment, then 2, 24, 48 and 72 hours after treatment.

What are the possible benefits and risks of participating?

All participants have a free diagnosis for intestinal parasitic infection and malaria infection. All

are treated and, if not cured by the drug provided, treated with the currently recommended drug (albendazole and praziquantel and malaria treatment according to local guidelines). Risks are represented by side effects linked to the treatment.

Where is the study run from?

1. Centre Suisse de Recherches Scientifiques (CSRS) (Côte d'Ivoire)
2. University Felix Houphouet Boigny (Université Félix Houphouët Boigny (UFHB)) (Côte d'Ivoire)

When is the study starting and how long is it expected to run for?

May 2015 to October 2015

Who is funding the study?

Rudolf Geigy Foundation (Switzerland)

Who is the main contact?

Prof J Keiser

Contact information

Type(s)

Scientific

Contact name

Prof Jennifer Keiser

Contact details

Socinstrasse 57

Basel

Switzerland

4002

Additional identifiers

Protocol serial number

01

Study information

Scientific Title

Assessment of the safety and efficacy of oral Moxidectin, Synriam®, Synriam®-Praziquantel combination versus Praziquantel in school children infected with *Schistosoma haematobium* and *Schistosoma mansoni*

Study objectives

The aim of this study is to assess the efficacy of Moxidectin and Synriam in treating schistosomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Northwest und Zentralschweiz Ethics Committee (Ethikkommission Northwest und Zentralschweiz EKNZ) ref: EKNZ UBE-15/01, 12/01/2015
2. National Ethics & Research Committee (Comite National d'Ethique et de la Recherche CNER) 16./06/2015

Study design

Randomised controlled phase 2 single blind trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schistosomiasis

Interventions

This study has four treatment arms - Two stool samples (study 1), three urine samples (study 2) and one blood finger prick sample will be collected if possible on two consecutive days or otherwise within a maximum of 5 days):

1. Moxidectin 8 mg single dose
2. Synriam® 150 mg (arterolane + 750 piperazine) for three consecutive days
3. Synriam® 150 mg (arterolane + 750 piperazine) for three consecutive days + praziquantel 40 mg/kg single dose
4. Praziquantel 40 mg/kg single dose

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Moxidectin, Synriam (arterolane + piperazine), Praziquantel

Primary outcome(s)

Efficacy: cure and egg reduction rate of *S. mansoni* and *S. haematobium*

Key secondary outcome(s)

1. Drug safety
2. Cure and egg reduction rate against possible co-infections (*Ascaris lumbricoides*, *Trichuris trichiura*, hookworm *Strongyloides stercoralis*)
3. To determine the efficacy of Synriam® against malaria infection

Completion date

01/10/2015

Eligibility

Key inclusion criteria

1. Written informed consent signed by parents and/or legal guardian, and oral assent by children
2. Able and willing to be examined by a study physician at the beginning of the study
3. Able and willing to provide two stool samples, three urine samples and one finger prick test at baseline and approximately three weeks after treatment (follow-up)
4. Positive for *S. mansoni* or *S. haematobium* eggs in the stool and/or in urine
5. Absence of major systemic illnesses (e.g. cancer, diabetes, clinical malaria or hepato-splenic schistosomiasis) as assessed by a medical doctor, upon initial clinical assessment
6. No known or reported history of chronic illness, e.g. cancer, diabetes, chronic heart, liver or renal disease
7. No anthelmintic or antimalarial treatments within past 4 weeks
8. No known allergy to study medications

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

1. No written informed consent by parents and/or legal guardian
2. Presence of any abnormal medical condition, judged by the study physician.
3. History of acute or severe chronic disease such as cancer, diabetes, chronic heart, liver or renal disease
4. Recent use of anthelmintic or antimalarial drugs (within past 4 weeks)
5. Attending other clinical trials during the study
6. Negative diagnostic result for *S. mansoni* or *S. haematobium* (absence of helminth eggs in stool/urine)

Date of first enrolment

04/05/2015

Date of final enrolment

15/05/2015

Locations**Countries of recruitment**

Côte d'Ivoire

Study participating centre

Centre Suisse de Recherches Scientifiques (CSRS) (Côte d'Ivoire)

Niangon Sud

Côte d'Ivoire

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Study participating centre

University Felix Houphouet Boigny (Université Félix Houphouët Boigny (UFHB)) (Côte d'Ivoire)

Abidjan

Côte d'Ivoire

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Sponsor information

Organisation

Geigy Foundation

Organisation

European Research Council

Funder(s)

Funder type

Research organisation

Funder Name

Rudolf Geigy Foundation (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	16/09/2016		Yes	No
Protocol (other)	16/09/2016	17/08/2023	No	No