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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

Registration date
19/07/2015

Overall study status
Completed

Last Edited
17/08/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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. Nordwest und Zentralschweiz Ethics Committee (Ethikkommission Nordwest 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

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 piperaquine) for three consecutive days
3. Synriam® 150 mg (arterolane + 750 piperaquine) 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 + piperaquine), Praziquantel

Primary outcome measure
Efficacy: cure and egg reduction rate of S. mansoni and S. haematobium

Secondary outcome measures
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

Overall study start date
04/05/2015

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 baselin 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 anthelminthic or antimalarial treatments within past 4 weeks
8. No known allergy to study medications

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
240

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 anthelminthic 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

Sponsor details
Socinstrasse 59
Basel
Switzerland
4002

Sponsor type
Research organisation

Organisation
European Research Council

Sponsor details
Covent Garden
Place Charles Rogier 16
1210 Saint-Josse-ten-Noode
Brussels
Belgium
1210

Sponsor type
Research council

Funder(s)

Funder type
Research organisation

Funder Name
Rudolf Geigy Foundation (Switzerland)

Results and Publications

Publication and dissemination plan
One manuscript will be submitted to a scientific journal by the end of 2015.

Intention to publish date
31/12/2015

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