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Efficacy and safety of increased dosage of praziquantel in treatment of schistosomiasis

Submission date 07/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/06/2005	**Overall study status** Completed	
Last Edited 28/01/2019	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00403611

Secondary identifying numbers
A30008: Tanzania (Master) (A20764: Brazil; A20805: Philippines; A30000: Mauritania)

Study information

Scientific Title
Efficacy and safety of increased dosage of praziquantel in treatment of schistosomiasis

Study objectives
The primary objective of this project is to evaluate the efficacy and safety of praziquantel 60 mg /kg in the treatment of schistosomiasis, as compared to the standard 40 mg/kg therapy in a representative community from a highly endemic area of schistosomiasis in Northeastern Brazil. Cure rates, reduction in egg counts and proportions of reported side-effects in children at the 10 - 19 years age-range with at least 100 eggs per gram of faeces will be compared between regimens, aiming to evaluate the superiority of 60 mg/kg over the 40 mg/kg dose currently recommended by the World Health Organization (WHO). Reinfection rates will also be evaluated aiming to improve transmission control within the local health system, including re-treatment combined with auxiliary control measures. Features related to the clinical, nutritional and immunological status of the patients prior to treatment will also be investigated in association with the outcome of praziquantel treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Schistosomiasis

Interventions
Praziquantel 60 mg/kg as single dose compared to standard 40 mg/kg as single dose.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Praziquantel

Primary outcome measure
1. Cure rate and egg reduction rate at 21 days after treatment
2. Reinfection rate and egg reduction rate at six and twelve months after treatment

Secondary outcome measures
1. Occurrence of the following symptoms following praziquantel administration:
1.1. Abdominal pain
1.2. Diarrhoea
1.3. Vomiting
1.4. Nausea
1.5. Drowsiness
1.6. General malaise
1.7. Oedema
1.8. Skin rash
1.9. Urticaria
1.10. Myalgia
1.11. Heartburn
1.12. Fever
1.13. Dizziness and headache
2. Weight (kg) and height (m) measured at day 0, 6 months and 12 months follow-up visits
3. Presence/absence of periportal fibrosis and liver or spleen enlargement at day 0, 6 months and 12 months follow-up visits
4. Factors associated with cure/failure at day 21 evaluation:
4.1. Haematological: haemoglobin/haematocrit, leukocytes count, lymphocytes and eosinophyles count
4.2. Biochemistry: liver function will be evaluated by serum bilirubin, alkaline phosphatase, aspartate aminotransferase, and alanine aminotransferase levels
4.3. Immunological: titres of anti-soluble egg antigen (anti-SEA) and anti-SWAB antibodies
5. Periportal fibrosis and liver/spleen enlargement

Overall study start date
18/02/2004

Completion date
18/02/2006

Eligibility

Key inclusion criteria
1. Subjects 10 - 19 years old
2. Harbouring at least 100 eggs per gram of faeces (epg)
3. Able and willing to follow-up and provide written informed consent

Participant type(s)
Patient

Age group

Child

Lower age limit
10 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
182

Key exclusion criteria
1. Pregnancy or lactation
2. Acute or chronic severe disease including hepato-splenic schistosomiasis
3. Use of praziquantel in the last 30 days
4. Known hypersensitivity associated with praziquantel
5. Current use of other medication that may affect the result of present trial e.g. antibiotics and corticosteroids

Withdrawal criteria:
Serious adverse event, intake of any other anti-schistosomal medication during the trial

Date of first enrolment
18/02/2004

Date of final enrolment
18/02/2006

Locations

Countries of recruitment
Brazil

Mauritania

Philippines

Switzerland

Tanzania

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
UNICEF/UNDP/World Bank/WHO - Special Programme for Research and Training in Tropical Diseases (TDR)

Sponsor details
20, Avenue Appia
Geneva -27
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CH 1211

Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)/World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

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	01/06/2011	28/01/2019	Yes	No