

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00403611

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 eosinophiles 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

Completion date

18/02/2006

Eligibility

Key inclusion criteria

1. Subjects 10 - 19 years old
2. Harboured 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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 Years

Upper age limit

19 Years

Sex

All

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)

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

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