

Randomised controlled trial of two different dosing regimens of praziquantel anti-bilharzia drug

Submission date 08/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/08/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/08/2019	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to compare the effectiveness and side effects of two different doses of the drug praziquantel for the treatment of *Schistosoma haematobium* parasite infection (bilharzia) in children.

Who can participate?

Primary school children in the two villages of Elkeriab and Tayba Elkababish , Khartoum State, who are affected with urinary bilharzia

What does the study involve?

Children randomly allocated to one of two different doses of praziquantel (the standard drug for bilharzia). *Schistosoma* eggs, blood in the urine and egg viability are measured by urine testing weekly for six weeks.

What are the possible benefits and risks of participating?

Praziquantel has been used for more than 30 years, with a good track record using the same doses used in this study. The children will benefit by getting treated for bilharzia with an effective and safe medicine. This drug can have minor side effects such as nausea, vomiting and skin rash, but side effects are not common.

Where is the study run from?

The study will be run and conducted in the villages of Elkeriab and Tayba Elkababish, East Nile Locality, Khartoum State, Sudan.

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

January 2017 to April 2017

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Prof. Abu Bakr Ibrahim
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PZQ 17

Study information

Scientific Title
Randomised controlled trial of two different dosing regimens of praziquantel for the treatment of Schistosoma haematobium in children

Acronym
PZQRCT

Study objectives
The higher dose of praziquantel is better than the standard dose in treating Schistosoma haematobium in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 07/01/2017, Ethics Committee of Khartoum State Ministry of Health, Sudan (Dr Mona Fath Alrahman Omer,
Directorate of the research Department, Khartoum Ministry of Health (KMOH); Tel +249 (0) 183760140; Email: ibtikar.Kmoh@gmail.com)

Study design

Single-centre blinded randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

School

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Urinary schistosomiasis in children

Interventions

Randomisation was computer-generated, allocation concealment using opaque brown envelopes. The children, their parents and the research assistant checking for the outcome were all blinded to the group allocation.

Two different dosing regimens of praziquantel were compared for the treatment of urinary schistosomiasis in children: a dose of 40 mg/kg vs 60 mg/kg. The 40 mg/kg was given in two equal doses four hours apart and the 60 mg/kg was divided into three equal doses four hours apart. The doses were administered by a doctor.

The patients were followed up weekly for a total duration of 6 weeks post intervention.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Praziquantel

Primary outcome measure

Schistosoma ova, haematuria and ova viability measured using urine test weekly for six weeks

Secondary outcome measures

Side effects of praziquantel assessed using patient interviews at week one

Overall study start date

15/01/2017

Completion date

01/04/2017

Eligibility

Key inclusion criteria

1. School age children (6-14 years of age)
2. Male and females
3. Positive urine test for Schistosoma ova
4. Lives in specific locality of Elkeriab and Tayba Elkababish, Khartoum State, Sudan

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

The population of the study was all the primary school children in the two primary schools (Elkeriab and Tayba Elkababish). The total number of school children was 1205 children, 105 students tested positive for urinary schistosomiasis, so were included in the trial.

Total final enrolment

105

Key exclusion criteria

1. Refused to participate in the study
2. Age less than 6 years or more than 14 years

Date of first enrolment

18/01/2017

Date of final enrolment

01/02/2017

Locations

Countries of recruitment

Sudan

Study participating centre

Elkeriab and Tayba Elkabaish primary schools

Elkeriab Village, East Nile Locality

Khartoum North

Sudan

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Sponsor information

Organisation

The National Ribat University

Sponsor details

Faculty of Laboratory Science

Buri

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Sponsor type

University/education

ROR

<https://ror.org/01x7yyx87>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The researchers will publish the final results of the study in the next few weeks.

Intention to publish date

01/10/2019

Individual participant data (IPD) sharing plan

Please contact Prof Abu Bakr Ibrahim (drabubakrhim@gmail.com) for access to the datasets, the data will be available from September 2019 for three months, the researchers have obtained consent from participants that data may be shared for research and educational purposes only.

IPD sharing plan summary

Available on request