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

**Submission date**
08/08/2019

**Recruitment status**
No longer recruiting

**Registration date**
28/08/2019

**Overall study status**
Completed

**Last Edited**
28/08/2019

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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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