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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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Side effects of praziquantel assessed using patient interviews at week one

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
14 years

Sex
All

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

ROR
https://ror.org/01x7yyx87

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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