

Effect of integrated interventions against schistosomiasis in rural Sudan

Submission date 05/01/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/01/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/01/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Moving from control to elimination of schistosomiasis is a paradigm shift that creates several challenges. Current interventions and strategies against schistosomiasis in many endemic countries were designed for morbidity control or the elimination of schistosomiasis as a “public health problem”. The interruption of schistosomiasis transmission is a long-term undertaking but requires significant changes in the approach, design and strategies with a focus on reducing transmission and preventing reinfection. This involves several challenges such as the implementation of intensified interventions, expansion of treatment coverage, use of alternative strategies, improvement of clean water supply, sanitation and hygiene, health education, funding for interventions, monitoring and evaluation, and strengthening of institutional capacities and surveillance response system. We aim to assess the effects of the integrated interventions of Community-Led Total Sanitation, Vector Control and Primary Health Care Strengthening on schistosomiasis prevalence, incidence and re-infection rate in rural areas of Sudan using a community-based study.

Who can participate?

In each community, children aged 5 to 15 and other age groups above 15 years are eligible

What does the study involve?

People in the intervention group will benefit from the community-led total sanitation, snail control interventions (snail survey and molluscicide application), and provision of praziquantel. In addition, the Primary Health Care system will be strengthened by training the health workforce to build the capacity for diagnosis and treatment of schistosomiasis and health information management, providing necessary equipment, consumables and medicines. The control group will benefit from the equivalent interventions after the study is completed. The Kato-Katz methods and circulating cathodic antigen methods will be used for testing for *Schistosoma mansoni* and urine centrifugation and dipstick methods will be used for *Schistosoma haematobium*.

What are the possible benefits and risks of participating?

The research participants will benefit from less exposure to the intermediate host (i.e. snails), improved access to a latrine and improved access to de-wormer at the health post or health

center level in their catchment areas. The main components of the project and also the research is to control infested snails, improve household latrine and improve the primary health care system. We do not expect any physical or psychological risks or side effects to participants or third parties due to the snail control, latrine improvement and increased accessibility to dewormer (praziquantel). There is no risk associated with stool and urine collection.

For snail control, molluscicide will be applied. We will use niclosamide, which is the only molluscicide for controlling snails approved by the World Health Organization and also the FMOH, Sudan. This molluscicide is examined and verified for its safety based on a number of experiments for such a long period and is widely used across the world. Niclosamide, sold under the brand name Niclocide among others, is a medication used to treat tapeworm infestations.

Where is the study run from?

Federal Ministry of Health will run the study in collaboration with the Blue Nile National Institute for Communicable Disease.

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

August 2022 to December 2023.

Who is funding the study?

This study is funded by the Korea International Cooperation Agency (KOICA).

Who is the main contact?

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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

Nil known

Study information

Scientific Title

Effect of integrated interventions combining mass drug administration, community-led total sanitation, vector control, and primary health care strengthening against schistosomiasis on prevalence, incidence and reinfection among school-aged children and adults in rural areas of White Nile, North Kordofan, Gezira, Blue Nile, Khartoum, and Kassal states, Sudan

Study objectives

Null hypothesis: Comprehensive interventions combining community-led total sanitation, vector control, and primary health care strengthening have no significant effect against schistosomiasis prevalence, incidence and re-infection.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/12/2022, National Research Ethics Review Committee of Federal Ministry of Health, Sudan (P.O. Box: 303, Postal code: 11111, Federal Ministry of Health, Khartoum, Sudan; +249 157845773; research.dep.fmoh@gmail.com), ref: 6-9-22

Study design

Community-based cluster-randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of schistosomiasis in school-aged children and adults in rural Sudan

Interventions

People in the intervention group will receive the interventions of community-led total sanitation, vector control, and primary health care strengthening from March 2023 through December 2023. During this period, the control group will not receive the interventions but they will benefit from equivalent interventions after the trial is completed. Pre-triggering, Triggering, Post-Triggering, Post Open Defection Free activities will be conducted for the community-led

total sanitation by the community-led total sanitation facilitators and village promoters in the intervention group. For vector control, molluscicide will be applied along the water contact points in the intervention group by the village vector control volunteers. For primary health care strengthening, health centers and health posts will benefit provision of diagnosis and treatment equipment and electronic devices for reporting the cases, and health professionals working for health centers and health posts will be trained on diagnosis and treatment of schistosomiasis and information management system by the experts of the directorate of primary health care strengthening of the Federal Ministry of Health, Sudan. One hundred communities will be randomized into the intervention and the control group with a 1:1 ratio using a computer program by an independent statistician. There is a 3-week recruitment period (baseline survey, January 2023), and two more rounds of the survey will be conducted at 6 months (August 2023) and 10 months (December 2023) after the baseline survey.

Intervention Type

Mixed

Primary outcome(s)

Schistosomiasis infection status measured using the following methods:

1. Schistosomiasis mansoni by Kato Katz methods and the circulating cathodic antigen (CCA) in January 2023 (baseline survey), and at 6 months (August 2023) and 10 months (December 2023) after the baseline survey
2. Schistosomiasis haematobium by urine centrifugation and dipstick methods in January 2023, and at 6 months (August 2023) and 10 months (December 2023) after the baseline survey

Key secondary outcome(s)

1. Latrine coverage measured using a household-based survey questionnaire in January 2023 (baseline survey), and at 6 months (August 2023) and 10 months (December 2023) after the baseline survey
2. Snail density measured using scooping methods with a standardized scoop comprised of a flat wire mesh size (1.5 mm mesh size) mounted on a metal frame (40×30 cm) with a 2 m long metal handle on a quarterly basis from March through December 2023

Completion date

31/12/2023

Eligibility

Key inclusion criteria

In each community, children aged 5–15 and other age group above 15 years are eligible.

Participant type(s)

All

Healthy volunteers allowed

No

Age group

All

Sex

All

Key exclusion criteria

People will be excluded from the study if they do not agree to be enrolled and/or examined.
People with diarrhea will be also excluded.

Date of first enrolment

22/01/2023

Date of final enrolment

22/02/2023

Locations**Countries of recruitment**

Sudan

Study participating centre

Communicable and Non-Communicable Diseases Control Directorate

Federal Ministry of Health, Sudan

Khartoum

Sudan

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Sponsor information**Organisation**

Korea International Cooperation Agency

ROR

<https://ror.org/0106d7657>

Funder(s)**Funder type**

Government

Funder Name

Korea International Cooperation Agency

Alternative Name(s)

KOICA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	questionnaire and informed consent form		11/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes