ISRCTN75328855 https://doi.org/10.1186/ISRCTN75328855

Effect of integrated interventions against schistosomiasis in rural Sudan

Submission date 05/01/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/01/2023	**Overall study status** Completed	
Last Edited 12/01/2023	**Condition category** Infections and Infestations	

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 de-wormer (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?
Seungman Cha, seungman.cha@handong.edu (South Korea)
Dalya Idris Hassan Eltayeb, dalyaeltayeb@gmail.com, Director General of Primary Health Care Directorate (Sudan)

Contact information

Type(s)
Scientific

Contact name
Prof Seungman Cha

ORCID ID
https://orcid.org/0000-0003-1264-3313

Contact details
Handong University
558, Handong-ro
Heunghae-eup
Buk-gu
Pohang-si
Gyeongsangbuk-do
Pohang
Korea, South
37554
+82 0542601784
seungman.cha@handong.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

See trial outputs table

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 measure
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

Secondary outcome measures
1. Latrine coverage meaured 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

Overall study start date
15/08/2022

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

Age group
All

Sex
Both

Target number of participants
The 100 communities will be randomized into the intervention or the control group using the STATA program, respectively. One hundred community members will be selected from each community (2 children: boys and girls; 2 adults: man and woman from a household; total 100 residents from 25 households in a community).

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
111

Sponsor information

Organisation
Korea International Cooperation Agency

Sponsor details
825 Daewangpangyo-ro Gyeonggi-do Seongnam-si
Seongnam-si
Korea, South
13449
+82-31-7400-114
prkoica@koica.go.kr

Sponsor type
Government

Website
http://www.koica.go.kr/english/main.html

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/03/2024

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