

# Surveys for assessment of urogenital schistosomiasis in pre-school, school-aged children, adolescents and adults in Zanzibar (Unguja and Pemba Islands)

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
21/07/2020	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
27/07/2020	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
30/12/2025	Infections and Infestations	

## Plain English summary of protocol

Current plain English summary as of 27/07/2020:

### Background and study aims

Urogenital schistosomiasis is a parasitic disease caused by the bloodfluke species *Schistosoma haematobium*. On the Zanzibar islands, belonging to the United Republic of Tanzania, considerable progress towards elimination of urogenital schistosomiasis was made over the course of the Zanzibar Elimination of Schistosomiasis Transmission (ZEST) project implemented from 2011 till 2017 (See <http://www.isrctn.com/ISRCTN48837681> for more details of this study). During the ZEST project, mass drug administration (MDA) with praziquantel was implemented biannually in schools and whole communities across Unguja and Pemba. In 30 randomly selected shehias (smallest administrative areas) on Unguja and Pemba, respectively, MDA was supplemented by snail control and behavioural change interventions. The impact of the interventions was monitored in annual cross-sectional surveys in 90 study schools and shehias from 2012 till 2017.

Within the ZEST project, urogenital schistosomiasis was eliminated as public health problem from most schools and communities in Zanzibar in 2017 and the *S. haematobium* prevalence was significantly reduced.

While snail control and behaviour change interventions of ZEST ceased in 2017, MDA in schools and shehia communities continued under the lead of the Neglected Diseases Program of the Zanzibar Ministry of Health. Together with the neglected tropical disease (NTD) programme, this study aims to monitor the *S. haematobium* infections in annual school-based and community-based cross-sectional surveys in 93 sites. The study will reveal whether MDA alone, without additional snail control and behaviour change interventions, is able to sustain or further reduce the low level of *S. haematobium* infections in Zanzibar.

### Who can participate?

The study will be implemented on Unguja and Pemba islands. Annual cross-sectional surveys will

be conducted in 93 schools and communities, respectively, from 2018 till 2021. Schoolchildren from nursery till grade 6 will be invited to participate in the school-based surveys. Participants aged 13 years and older will be eligible to participate in the community-based surveys.

**What does the study involve?**

Participants will be tested for *S. haematobium* infection and blood in urine. Participants will be invited to answer a questionnaire about their past anti-schistosomal treatments and behaviours that might put them on risk for infection.

**What are the possible benefits and risks of participating?**

The direct benefit from participation in the study is that participants will be informed about their *S. haematobium* infection status and will receive treatment with praziquantel if positive. The treatment can improve the general health status, including less pain, fatigue and weakness and thus improved school or working performance.

For the study participants, no risks are involved in producing a fresh urine sample. The questionnaires will include some questions that might be embarrassing, discomforting or too personal; however, participants can deny responding to these questions when they decide to participate.

**Where is the study run from?**

Swiss Tropical and Public Health Institute (Switzerland), Public Health Laboratory-Ivo de Carneri (Pemba, Tanzania), and Zanzibar Neglected Diseases Programme (Unguja, Tanzania)

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

From January 2017 to December 2022

**Who is funding the study?**

Bill and Melinda Gates Foundation (USA)

**Who is the main contact?**

Dr Stefanie Knopp  
[s.knopp@swisstph.ch](mailto:s.knopp@swisstph.ch)

**Previous plain English summary:**

**Background and study aims**

Urogenital schistosomiasis is a parasitic disease caused by flatworms such as *Schistosoma haematobium* that are released by freshwater snails. On the Zanzibar islands, belonging to the United Republic of Tanzania, considerable progress towards elimination of urogenital schistosomiasis was made over the course of the Zanzibar Elimination of Schistosomiasis Transmission (ZEST) project implemented from 2011 till 2017. During the ZEST project, mass drug administration (MDA) with praziquantel was implemented biannually in schools and whole communities across Unguja and Pemba. In 30 randomly selected shehias (smallest administrative areas) on Unguja and Pemba, respectively, MDA was supplemented by snail control and behavioural change interventions. The impact of the interventions was monitored in annual cross-sectional surveys in 90 study schools and shehias from 2012 till 2017.

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Stefanie Knopp

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**Contact details**

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s.knopp@swisstph.ch

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Version 1.0 (03.06.2019)

## Study information

**Scientific Title**

Repeated cross-sectional surveys for monitoring urogenital schistosomiasis in pre-school, school-aged children, adolescents and adults in Zanzibar (Unguja and Pemba Islands)

**Acronym**

ZNZ\_PS

**Study objectives**

Biannual mass drug administration (MDA) alone, without additional snail control and behaviour change interventions, is able to sustain, or further reduce, the low level of *S. haematobium* infections in Zanzibar.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Approved 01/02/2017, Zanzibar Medical Research and Ethics Committee (ZAMREC) (Ministry of Health Zanzibar, PO Box 236, Vuga, Zanzibar, United Republic of Tanzania), Ref: ZAMREC 0003 /SEPTEMBER/011
2. Approved April 20/04/2018, Zanzibar Medical Research and Ethics Committee (ZAMREC) (Ministry of Health Zanzibar, PO Box 236, Vuga, Zanzibar, United Republic of Tanzania), Ref: NO. ZAMREC/0001/FEBRUARY/18
3. Approved 12/06/2019, Zanzibar Health Research Ethics Institute (ZAHRI) (Ministry of Health Zanzibar, PO Box 236, Vuga, Zanzibar, United Republic of Tanzania; [info@zahri.org](mailto:info@zahri.org); +255 772 605560), Ref: NO.ZAHREC/02/JUNE/2019/36

4. Approved 10/07/2019, Ethics Committee Northwest and Central Switzerland (EKNZ) (Hebelstrasse 53, 4056 Basel, Switzerland; eknz@bs.ch; +41 61 2681350), Ref: Req-2019-00524
5. Approved 22/10/2020, Zanzibar Health Research Ethics Institute (ZAHRI) (Ministry of Health Zanzibar, PO Box 236, Vuga, Zanzibar, United Republic of Tanzania; info@zahri.org; +255 772 605560), Ref: NO.ZAHREC/01/RN/OCT/2020/08

### **Study design**

Repeated cross-sectional surveys in communities and schools to monitor the *Schistosoma haematobium* prevalence and infection intensity in the study population.

### **Primary study design**

Observational

### **Study type(s)**

Screening

### **Health condition(s) or problem(s) studied**

*Schistosoma haematobium* infections (urogenital schistosomiasis)

### **Interventions**

The *S. haematobium* prevalence will be determined annually (2018, 2019, 2020, 2021) in cross-sectional surveys conducted in schools and communities of the study area.

Mass drug administration with praziquantel (40 mg/kg) is carried out as part of the routine interventions of the Neglected Tropical Diseases Programme (NTD) of the Zanzibar Ministry of Health at least once per year. In community-based treatment, trained drug distributors use a door-to-door approach to provide praziquantel to all community members aged >3 years that did not receive praziquantel in the same treatment round via school-based treatment, and are not severely sick. In school-based treatment, trained teachers provide directly-observed praziquantel treatment to the children attending school on the day of treatment. Community drug distributors and teachers are supervised by the staff of the NTD Programme.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Praziquantel

### **Primary outcome(s)**

Current primary outcome measure as of 27/07/2020:

Number of *S. haematobium* infected individuals detected by the urine filtration method (detecting *S. haematobium* eggs in 10 ml urine) and reagent strip method (Hemastix; detecting microhaematuria in urine) applied on a single urine sample per participant in each annual cross-sectional survey in 2018, 2019, 2020, and 2021

Previous primary outcome measure:

Number of *S. haematobium* infected individuals detected by the urine filtration method (detecting *S. haematobium* eggs in 10 ml urine) and reagent strip method (Hemastix; detecting

microhaematuria in urine) applied on a single urine sample per participant in each cross-sectional survey at 0, 1, 2, and 3 years

### **Key secondary outcome(s)**

Current secondary outcome measures as of 27/07/2020:

1. Impact of mass drug administration (MDA) with praziquantel (40 mg/kg) over time measured in 2018, 2019, 2020, and 2021 during the annual cross-sectional school-based and community-based surveys using:
  - 1.1. *S. haematobium* prevalence measured by urine filtration (*S. haematobium* egg absence/presence in 10 ml urine) and measured by reagent strips to assess microhaematuria absence/presence
  - 1.2. *S. haematobium* infection intensity measured by urine filtration (*S. haematobium* egg counts in 10 ml urine)
2. Age-prevalence distribution by age and stratified by sex, measured by urine filtration and reagent strips, sex and age will be recorded on enrolment and in 2018, 2019, 2020, and 2021 during the annual cross-sectional school-based and community-based surveys
3. Treatment coverage and compliance of MDA with praziquantel (40 mg/kg) preceding the cross-sectional survey, determined with questionnaires in annual cross-sectional surveys (coverage is defined as the percentage of those queried receiving praziquantel tablets during MDA, and compliance is defined as the percentage of those queried swallowing praziquantel tablets in the dose supplied during MDA) in 2018, 2019, 2020, and 2021
4. Risk factors for *S. haematobium* infection determined with questionnaires (query the use of natural open freshwater bodies for washing, bathing and household chores, travel, location of residence and demographic factors) during annual cross-sectional surveys in 2018, 2019, 2020, and 2021

Previous secondary outcome measures:

1. Impact of mass drug administration (MDA) with praziquantel (40 mg/kg) over time measured at 0, 1, 2 and 3 years during the annual cross-sectional school-based and community-based surveys using:
  - 1.1. *S. haematobium* prevalence measured by urine filtration (*S. haematobium* egg absence/presence in 10 ml urine) and measured by reagent strips to assess microhaematuria absence/presence
  - 1.2. *S. haematobium* infection intensity measured by urine filtration (*S. haematobium* egg counts in 10 ml urine)
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4. Risk factors for *S. haematobium* infection determined with questionnaires (query the use of natural open freshwater bodies for washing, bathing and household chores, travel, location of residence and demographic factors) during annual cross-sectional surveys at 0, 1, 2 and 3 years

### **Completion date**

31/12/2022

## **Eligibility**

## **Key inclusion criteria**

1. Children attending the selected nurseries and schools
2. Adolescents or adults aged  $\geq 13$  years from the selected shehias, including pregnant women, only one adolescent and/or adult per household eligible
3. Submitted informed consent form (ICF) signed by a parent or legal guardian in case of participating children and adolescents, or signed by the participant in case of participating adults
4. Able to provide one urine sample with sufficient volume to perform diagnostic tests

## **Participant type(s)**

Other

## **Healthy volunteers allowed**

No

## **Age group**

Mixed

## **Lower age limit**

13 years

## **Upper age limit**

100 years

## **Sex**

All

## **Total final enrolment**

91253

## **Key exclusion criteria**

Does not meet inclusion criteria

## **Date of first enrolment**

15/02/2018

## **Date of final enrolment**

31/07/2021

## **Locations**

### **Countries of recruitment**

Tanzania

### **Study participating centre**

Public Health Laboratory – Ivo de Carneri (PHL-IdC)

P.O. Box 122

Wawi, Pemba  
Tanzania

**Study participating centre**  
**Neglected Diseases Programme**  
P.O.Box 236  
Zanzibar Town, Unguja  
Tanzania

## Sponsor information

**Organisation**  
Swiss Tropical and Public Health Institute

**ROR**  
<https://ror.org/03adhka07>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Bill and Melinda Gates Foundation

**Alternative Name(s)**  
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United States of America

# Results and Publications

## Individual participant data (IPD) sharing plan

### 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?
<a href="#">Basic results</a>		12/12/2025	30/12/2025	No	No
<a href="#">Interim results article</a>		12/02/2021	31/08/2021	Yes	No