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

Submission date
21/07/2020

Recruitment status
No longer recruiting

Registration date
27/07/2020

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[X] Individual participant data
[X] Record updated in last year

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 thebloodfluke 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

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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Who is the main contact?
Dr Stefanie Knopp
s.knopp@swisstph.ch

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; +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

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

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet.

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 measure

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

Secondary outcome measures

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)
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 at 0, 1, 2 and 3 years 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) at 0, 1, 2 and 3 years

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

Overall study start date
01/01/2017

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Children attending the selected nurseries and schools
2. Adolescents or adults aged ≥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

Age group
Mixed

Sex
Both

Target number of participants
In each annual cross-sectional survey, we will enrol ~6,510 adolescents and adults in the community and ~20,460 children in schools.

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

Sponsor details
Socinstrasse 57
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Switzerland
4002
+41 61 2848 961
hsr-desk@swisstph.ch

Sponsor type
Research organisation

Website
http://www.swisstph.ch/

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, 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

Publication and dissemination plan
We intend to publish our study results in the peer-reviewed (whenever possible open-access) literature and international conferences by the end of 2022.

Intention to publish date
31/12/2022

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?
Interim results article		12/02/2021	31/08/2021	Yes	No
Dataset			06/08/2024	No	No