# Study and implementation of urogenital schistosomiasis elimination in Zanzibar (Unguja and Pemba islands)

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/08/2012		[X] Protocol		
<b>Registration date</b> 05/09/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 11/10/2022	Condition category Infections and Infestations	Individual participant data		

# Plain English summary of protocol

Background and study aims

Schistosomiasis is an infection caused by parasites that live in freshwater snails. It continues to be a major public health problem in many developing countries. However, illness due to schistosomiasis has been greatly reduced in some parts of the world, including Zanzibar. Over the next 3-5 years, the whole at-risk population on Unguja and Pemba islands will be given the drug praziquantel twice a year to treat schistosomiasis infection. Strategies to control the snails that carry the parasites and also to change people's behaviour will be carried out in selected communities. The impact and outcome of the these three interventions will be compared to provide evidence for decisions about schistosomiasis elimination not only for the Zanzibar, but also for other settings in Africa and elsewhere.

#### Who can participate?

45 randomly selected communities on Unguja and Pemba islands

#### What does the study involve?

The communities are randomly allocated to one of three groups. All three groups are treated with praziquantel. One of the groups receives no additional treatment. The second group receives niclosamide (a pesticide against snails) twice-yearly to reduce the population of snails that carries the parasites. The third group receives interventions to trigger behaviour change. Changes in knowledge, attitudes and practices are assessed annually through focus group discussions and in-depth interviews with schoolchildren, teachers, parents and community leaders. Changes in the levels of infection are assessed annually and outcomes compared between the three groups. Changes in the health system, water and sanitation infrastructure are annually tracked by interviews with community leaders. Additional issues potentially impacting on study outcomes and all incurring costs are monitored and recorded.

# What are the possible benefits and risks of participating?

The direct benefit to the whole at-risk population in Zanzibar including our study participants is reduced illness caused by schistosomiasis infections. Praziquantel is generally well tolerated. Side effects are typically mild and short-lived and do not require treatment. The following side

effects may be observed: discomfort, headache, dizziness, feeling sick, rise in temperature and, rarely, hives.

Where is the study run from?

The study is jointly run by:

- 1. Natural History Museum London (UK)
- 2. Swiss Tropical and Public Health Institute (Switzerland)
- 3. Centers for Disease Control and Prevention (USA)
- 4. Helminth Control Laboratory Unguja of the Zanzibar Ministry of Health and the Public Health Laboratory-Ivo de Carneri in Pemba (Tanzania)

When is the study starting and how long is it expected to run for? November 2011 to December 2017

Who is funding the study?

SCORE at the University of Georgia Research Foundation (UGARF) through the Bill and Melinda Gates Foundation (USA)

Who is the main contact?

1. Prof. David Rollinson

d.rollinson@nhm.ac.uk

2. Dr Stefanie Knopp

s.knopp@swisstph.ch

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof David Rollinson** 

#### **ORCID ID**

https://orcid.org/0000-0003-1999-1716

#### Contact details

Natural History Museum Cromwell Road London United Kingdom SW7 5BD +44 (0)20 7942 5181 d.rollinson@nhm.ac.uk

## Type(s)

Scientific

#### Contact name

Dr Stefanie Knopp

#### **ORCID ID**

#### https://orcid.org/0000-0001-5707-7963

#### Contact details

Swiss Tropical and Public Health Institute Socinstrasse 57 Basel Switzerland CH-4051 +41 (0)61 284 8727 s.knopp@swisstph.ch

# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

N/A

# Study information

#### Scientific Title

Study and implementation of urogenital schistosomiasis elimination in Zanzibar (Unguja and Pemba islands) using an integrated multidisciplinary approach

# Study objectives

Applying periodic treatment with praziquantel to the whole eligible population (exclusion of children <3 years, pregnant women and severely sick people) at risk of S. haematobium, plus snail control using a molluscicide (niclosamide) and environmental management, plus behaviour change interventions will result in:

- 1. Elimination of schistosomiasis as a public health problem in 3 years and interruption of transmission in 5 years in Unguja
- 2. Control of schistosomiasis (prevalence <10%) in 3 years and elimination of schistosomiasis as a public health problem in 5 years in Pemba

# Added 25/03/2019:

In line with the trial design, the trial hypothesis is: Snail control or behaviour change interventions in addition to periodic mass treatment with praziquantel will be more effective in reducing the S. haematobium prevalence and intensity than mass drug administration alone.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

- 1. Ethikkommission beider Basel, Switzerland, 08/08/2011, ref: 236/11
- 2. Zanzibar Medical Research Ethical Committee of the Zanzibar Ministry of Health (ZAMREC, United Republic of Tanzania, 29/09/2011, ref: ZAMREC/0003/Sept/011
- 3. Institutional Review Board of the University of Georgia, USA, 27/10/2011, ref: 2012-10138-0

#### Study design

Randomised intervention trial with three study arms

#### Primary study design

Interventional

# Study type(s)

Treatment

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

Schistosoma haematobium infections

#### **Interventions**

The study will be implemented in 45 shehias in both Unguja and Pemba. Among the 45 shehias on each island 15 were randomly assigned to one of the following three intervention arms:

- 1. Treatment per the National Plan of the Zanzibar Ministry of Health (twice yearly preventive chemotherapy with praziquantel, including social mobilization and education)
- 2. Treatment per the National Plan plus snail control
- 3. Treatment per the National Plan plus intensive behaviour change interventions

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

Current primary outcome measure as of 25/03/2019:

S. haematobium infection prevalence and intensity based on urine filtration results in 9- to 12-year-old children after five years of follow-up (i.e. at the 5-year endline survey in 2017)

Previous primary outcome measure:

Elimination of urogenital schistosomiasis in Unguja and reduction of the S. haematobium prevalence <10% in Pemba after 5 years of interventions

# Key secondary outcome(s))

- 1. Prevalence and intensity of S. haematobium infections in 9-12-year-old schoolchildren and antibody levels against S. haematobium in first-year students, hence judging current infection status and history of exposure, and prevalence and intensity of S. haematobium infections in adults and first-year students
- 2. Impact of niclosamide on snail populations, schistosome transmission and reinfection of the Zanzibari population
- 3. Changes in the behaviour of the human population associated with parasite transmission
- 4. Sensitivity and specificity of novel diagnostic methods

#### Completion date

31/12/2017

# **Eligibility**

#### Key inclusion criteria

- 1. Schoolchildren, either male or female, aged 9-12 years, attending the selected schools (in each study year)
- 2. First-year students, either male or female, attending the selected schools (in years 1 and 5)
- 3. Adults aged 20-55 years from the selected communities (shehias), only one adult per household, pregnant women are eligible (in years 1 and 5)
- 4. Submitted written informed consent sheet signed by parent or legal guardian in case of participating children or signed by the participant in case of participating adults
- 5. Oral assent from participant given
- 6. One urine sample provided (from 9-12-year old children in each study year; from first-year students and adults in years 1 and 5)
- 7. One blood sample obtained (from first-year students in years 1 and 5)

#### Participant type(s)

Αll

#### Healthy volunteers allowed

No

#### Age group

Child

#### Sex

Αll

#### Key exclusion criteria

- 1. Children not attending the selected schools
- 2. Children not aged 9-12 years (in years 2, 3, and 4)
- 3. Children not aged 9-12 years or being first-year students (in years 1 and 5)
- 4. Adults not resident in the selected shehias
- 5. Adults aged <20 or >55 years (in years 1 and 5)
- 6. Written informed consent not submitted or not signed by parent or legal guardian in case of participating children or not signed by the participant in case of participating adults
- 7. No oral assent given
- 8. No urine sample provided (for 9-12-year old children in each study year; for first-year students and adults in years 1 and 5)
- 9. No blood sample obtained (from first-year students in years 1 and 5)

#### Date of first enrolment

01/11/2011

#### Date of final enrolment

31/05/2017

# Locations

#### Countries of recruitment

United Kingdom

England

Switzerland

Tanzania

# Study participating centre Natural History Museum

Cromwell Road London United Kingdom SW7 5BD

# Study participating centre Ministry of Health Zanzibar

Neglected Disease Control Program PO Box 236 Unguja Zanzibar Town Tanzania

\_

# Study participating centre Public Health Laboratory – Ivo de Carneri

PO Box 122 Wawi Chake Chake Pemba Tanzania

-

# Study participating centre Swiss Tropical and Public Health Institute

Socinstrasse 57 Basel Switzerland CH-4051

# Sponsor information

#### Organisation

Natural History Museum (UK)

#### **ROR**

https://ror.org/039zvsn29

# Funder(s)

# Funder type

University/education

#### **Funder Name**

University of Georgia Research Foundation Inc. (USA)

#### **Funder Name**

World Health Organization (Switzerland)

#### Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , BO3, OMS

### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

International organizations

#### Location

Switzerland

#### **Funder Name**

The Schistosomiasis Control Initiative (UK)

#### **Funder Name**

Bayer S.A.S. (France)

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available after publication upon request from The Schistosomiasis Consortium for Operational Research and Evaluation (SCORE). Data Request Form can be requested from the SCORE secretariat (Jennifer Deen Castleman, jdcastle@uga.edu). Data will be shared after publication and once the SCORE Data Request Form has been evaluated and signed by all relevant parties.

# IPD sharing plan summary

Available on request

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	results	17/10 /2013		Yes	No
Results article	results	14/05 /2015		Yes	No
Results article	results	20/08 /2015		Yes	No
Results article	results	04/01 /2016		Yes	No
Results article	results	11/07 /2016		Yes	No
Results article	results	01/09 /2016		Yes	No
Results article	results	01/11 /2016		Yes	No
Results article	results	16/12 /2016		Yes	No
Results article	results	23/10 /2018		Yes	No
Results article	results	01/08 /2019	02/07 /2019	Yes	No
Results article	results	06/05 /2019	03/01 /2020	Yes	No
Results article	qPCR results	04/09 /2020	07/09 /2020	Yes	No
Results article	Population genetic analysis of Schistosoma haematobium		11/10 /2022	Yes	No
Protocol article	protocol	30/10 /2012		Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes