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

Submission date
28/08/2012

Recruitment status
No longer recruiting

Registration date
05/09/2012

Overall study status
Completed

Last Edited
11/10/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study website
https://score.uga.edu/projects/elimination-of-schistosomiasis/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/11/2011

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)
All

Age group
Child

Sex
Both

Target number of participants
72000

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
England

Switzerland

Tanzania

United Kingdom

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)

Sponsor details
Cromwell Road
London
United Kingdom
SW7 5BD

Sponsor type
Research organisation

Website
http://www.nhm.ac.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, , ВОЗ, OMS

Funding Body Type
Private sector 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

Publication and dissemination plan
The trialists intend to publish our study results in the peer-reviewed (whenever possible open-access) literature before the end of 2018.

Updated 26/03/2019: The investigators intend to publish the study results in the peer-reviewed open access literature before the end of 2019.

Intention to publish date
31/12/2019

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

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Protocol article	protocol	30/10/2012		Yes	No
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