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Efficacy of a moxidectin versus ivermectin in subjects infected by Strongyloides stercoralis

Submission date	Recruitment status	[X] Prospectively registered
04/04/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/02/2019	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Strongyloides stercoralis, commonly referred to as threadworms, is a type of parasitic worm that infects the large intestines. S. stercoralis can cause a range of gastrointestinal (gut) symptoms, including nausea, pain and diarrhoea, and long-term infections can lead to disabling complications such as anaemia, stunted growth and slow mental development. S. stercoralis infections are very common in south East Asia and affect mainly adults. At the moment the most effective drug against the infection is ivermectin (a medication used to treat a range of different parasitic infections). The aim of this study is to find out whether the medication moxidectin (a drug designed specifically to kill parasitic worms) is active against the worm in the human body.

Who can participate?
Adults with a S. stercoralis infection

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive a single dose of 8mg moxidectin. Participants in the second group receive a single dose of 200ug /kg ivermectin. At the start of the study and 21 days after treatment, participants provide stool samples so that the severity of the infection can be measured. Participants are also asked to report any unwanted side-effects from the medications 3, 24, 48 and 72 hours after treatment.

What are the possible benefits and risks of participating?
Participants will benefit from receiving a free medical examination and treatment. There are no risks of participating as the study medications have been used before and no major side effects have been reported.

Where is the study run from?
Local villages in Champasack province (Laos)

When is the study starting and how long is it expected to run for?
December 2015 to June 2016

Who is funding the study?
European Research Council (Belgium)

Who is the main contact?
Prof. Jennifer Keiser

Contact information

Type(s)
Scientific

Contact name
Prof Jennifer Keiser

Contact details
Swiss Tropical and Public Health Institute (Swiss TPH)
Socinstr. 57
Basel
Switzerland
4051

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of moxidectin vs ivermectin against Strongyloides stercoralis infections: a randomised parallel trial

Study objectives
The aim of this study is to assess the first time the efficacy of oral moxidectin against S. stercoralis infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical comittee of Northern and Central Switzerland, 07/12/2015, ref: EKNZ UBE-15/103
2. Ministry of Health, National Institute of Public Health, Lao People's Democratic Republic, 11 /01/2016, ref: NIOPH/NECHR 075

Study design
Single-blind phase 2 randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Strongyloides stercoralis infection

Interventions
Subjects will be randomly assigned to one of the two treatment arms:
Group 1: Participants receive a single dose of ivermectin 200 ug/kg.
Group 2: Participants receive a single dose of moxidectin 8 mg.

Follow up will be carried out 21 days after the treatment and involves the provision of two stool samples.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Moxidectin, ivermectin

Primary outcome measure
Strongyloides stercoralis infection status is determined 21 days after treatment using the Baermann method in 2 stool samples.

Secondary outcome measures
1. Adverse events are measured through self-reporting 3, 24, 48 and 72 hours after treatment
2. S. stercoralis infection intensity is measured using a larval count in stool samples 21 days after treatment in relation to baseline infection intensity (LRR)
3. O. viverrini and other helminth infection status and intensity is measured using stool samples (Kato Katz method) 21 days after treatment

Overall study start date

01/12/2015

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Infected with S. stercoralis infection
3. Absence of major systemic illnesses
4. Written informed consent signed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 infected subjects

Key exclusion criteria
1. Abnormal medical conditions or chronic disease
2. Negative diagnostic result for soil-transmitted helminthes infection
3. No written informed consent
4. Recent anthelminthic treatment (past 2 months)
5. Pregnancy

Date of first enrolment
21/04/2016

Date of final enrolment
06/05/2016

Locations

Countries of recruitment
Lao People's Democratic Republic

Study participating centre

National Institute of Public Health
Vientiane
Lao People's Democratic Republic
01

Sponsor information

Organisation
Swiss Tropical and Public Health Institute (Swiss TPH)

Sponsor details
Socinstr. 57
Basel
Switzerland
4051

Sponsor type
University/education

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Research council

Funder Name
European Research Council

Alternative Name(s)
ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/07/2017		Yes	No
Results article	results from embedded study	26/03/2018		Yes	No