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Efficacy and safety of of tribendimidine against hookworm infections in children: a randomized controlled trial

Submission date
19/05/2017

Recruitment status
No longer recruiting

Registration date
19/05/2017

Overall study status
Completed

Last Edited
04/01/2019

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parasitic worms are organisms that live in the intestine and feed off their living hosts. There are many types of parasitic worms, including the hookworm. They are among the most common type of infections worldwide, especially in poor and deprived communities. They are spread by eggs present in human faeces which in turn contaminate soil in areas where sanitation is poor. An infection can cause malnutrition, physical and mental retardation, and reduced work performance in older age. Few drugs are available which are widely used in the treatment of parasitic worm infections and drug resistance is a growing problem. Tribendimidine is a broad-spectrum anti-parasitic worm drug which has been developed in China. The aim of this study is to find out the best dose of this drug to give to children with hookworm infections.

Who can participate?
Children aged between six and twelve years who have hookworm eggs in their stool.

What does the study involve?
Participants are randomly allocated to one of five groups. Those in the first group receive a single dose of 100 mg tribendimidine. Those in the second group receive a single dose of 200 mg tribendimidine. Those in the third group receive a split 200 mg tablet of tribendimidine. Those in the next group receive a single dose of a placebo (dummy drug). 21 days after receiving the treatment, participants provide a stool sample which is then tested for signs of parasitic worm eggs. Participants are also interviewed before treatment, 3 and 24 hours after treatment about whether they have experienced any side effects.

What are the possible benefits and risks of participating?
All participants benefit from receiving a clinical examination and hookworm infection treatment. STHs. All participating children remaining positive for hookworm at the end of the study will be treated with another medication (according to WHO recommendations). There are no notable risks involved with participating.

Where is the study run from?
Rubino Health Center (Cote d'Ivoire)

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

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

Who is the main contact?
Professor Jennifer Keiser
jennifer.keiser@unibas.ch

Contact information

Type(s)
Scientific

Contact name
Prof Jennifer Keiser

Contact details
Swiss Tropical and Public Health Institute
Socinstrasse 57
Basel
Switzerland
4051
+41 612 848 218
jennifer.keiser@unibas.ch

Additional identifiers

Protocol serial number
v.1.02

Study information

Scientific Title
Efficacy and safety of ascending dosages of tribendimidine against hookworm and concomitant soil-transmitted helminth infections in children: a randomized controlled trial

Study objectives
The aim of this study is to compare the efficacy and safety of three oral tribendimidine dosages (100 mg, 200 mg and 400 mg) versus placebo in school-aged children infected with hookworm and to measure tribendimidine disposition using dried blood spot technology.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Ethics committee of Northwestern and Central Switzerland (EKNZ) 03/04/2017, ref: 2017-00139
2. Ministere de la Sante et de hygiene publique, comite nationa d'ethique de la recherche, 17/04/2017, ref: 053/IMSHP/CNER-kp

Study design
Single blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hookworm infection

Interventions
Current interventions as of 25/07/2017:
Single, oral tribendimidine 100, 200 and 400 mg and placebo.

Patients will be randomized using block randomization to one of four groups.

Intervention group 1: Participants receive a single dose of oral tribendimidine 100 mg
Intervention group 2: Participants receive a single dose of oral tribendimidine 200 mg
Intervention group 4: Participants receive a single dose of oral tribendimidine 400 mg
Control group: Participants receive a single dose of a placebo

Follow up will be conducted for all treatment arms 21 days after treatment.

Previous interventions:
Single, oral tribendimidine 100, 200 and 400 mg and placebo.

Patients will be randomized using block randomization to one of four groups.

Intervention group 1: Participants receive a single dose of oral tribendimidine 100 mg
Intervention group 2: Participants receive a single dose of oral tribendimidine 200 mg
Intervention group 3: Participants receive a single dose of oral tribendimidine 200 mg split tablet
Intervention group 4: Participants receive a single dose of oral tribendimidine 400 mg
Control group: Participants receive a single dose of a placebo

Follow up will be conducted for all treatment arms 21 days after treatment.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Tribendimidine

Primary outcome(s)
Cure rate (conversion from being egg positive pre-treatment to egg negative post-treatment) against hookworm infection will be assessed using the quadruple Kato-Katz method at 21 days post-treatment.

Key secondary outcome(s))
1. Egg reduction rate against hookworm infection will be assessed using the quadruple Kato-Katz method at 21 days post-treatment
2. Cure and egg reduction rate against concomitant soil-transmitted helminths will be assessed using the quadruple Kato-Katz method at 21 days post-treatment
3. Safety will be assessed with evaluation of adverse events of the treated subjects based on interviews at 3 and 24 hours after treatment
4. Pharmacokinetic parameters: drug concentrations will be measured with a validated LC/MS method at baseline, 2, 3, 4, 5, 6, 7, 7.5, 8.5 and 24 hours post-dosing

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Written informed consent signed by parents and/or legal representative; and oral assent by child
2. Able and willing to be examined by a study physician at the beginning of the study
3. Able and willing to provide two stool samples at the beginning (baseline) and approximately three weeks after treatment (follow-up)
4. Positive for hookworm eggs in the stool
5. Absence of major systemic illnesses, e.g. diabetes, severe anemia, clinical malaria as assessed by a medical doctor, upon initial clinical assessment
6. No known or reported history of chronical illness as cancer, diabetes, chronic heart, liver or renal disease
7. No recent anthelminthic treatment (within past 4 weeks)
8. No known allergy to tribendimidine
9. Age range is 6-12 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. No written informed consent by parents and/or legal representative
2. Presence of major systemic illnesses, e.g. diabetes, severe anemia, clinical malaria as assessed by a medical doctor, upon initial clinical assessment
3. History of acute or severe chronic disease
4. Recent use of anthelminthic drug (within past 4 weeks)
5. Attending other clinical trials during the study
6. Negative diagnostic result for hookworm eggs in the stool

Date of first enrolment
25/05/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Côte d'Ivoire

Study participating centre
Rubino Health Center
Rubino
Côte d'Ivoire
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Sponsor information

Organisation
Swiss Tropical and Public Health Institute

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Government

Funder Name
European Research Council

Alternative Name(s)
The European Research Council, ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from jennifer.keiser@unibas.ch

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/08/2018		Yes	No
Results article	results	16/08/2019		Yes	No
Basic results		04/01/2019	04/01/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes