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Efficacy and safety of ivermectin against Trichuris trichiura

Submission date
19/05/2017

Recruitment status
No longer recruiting

Registration date
19/05/2017

Overall study status
Completed

Last Edited
13/03/2019

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. 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. Ivermectin (a medication used to treat a range of parasitic worm infections), may be useful when used in combination with other medications. The aim of this study is to find the best dose of ivermectin to use in the treatment of parasitic worm infections.

Who can participate?
Adults, pre-school children and school age children with a parasitic worm infection.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a single dose of a placebo (dummy drug). Those in the second group receive a single dose of ivermectin. The dose will vary depending on the age of the participant. 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, 24, and 72 hours after treatment about whether they have experienced any side effects.

What are the possible benefits and risks of participating?
All participants will benefit from a clinical examination and a treatment against parasitic worm infections. In addition, all participants who do not respond to treatment will receive treatment with a different drug (according to WHO recommendations). Ivermectin is a well-known, widely used drug and has very few, mild side effects. Therefore there are no significant risks involved with taking part.

Where is the study run from?
Hôpital Méthodiste de Dabou (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?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Professor Jennifer Keiser
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.02

Study information

Scientific Title
Efficacy and safety of ascending dosages of ivermectin against Trichuris trichiura in preschool- and school-aged children: a randomized controlled trial

Study objectives
Study aims:
1. To determine pharmacokinetic parameters in 10 adult patients infected with T. trichiura using whole blood, plasma, dried blood spots (DBS) and Mitra® allowing the determination of the best microsampling technology.
2. To compare the efficacy and safety of oral ivermectin dosages: i) 100 µg/kg and ii) 200 µg/kg versus iii) placebo in preschoolers infected with T. trichiura and to measure ivermectin disposition using a microsampling technology (DBS or Mitra®).
3. To compare the efficacy and safety of oral ivermectin dosages: i) 200 µg/kg ii) 400 µg/kg and iii) 600 µg/kg versus vi.) placebo in school-aged children infected with T. trichiura and to measure ivermectin disposition using a microsampling technology (DBS or Mitra®).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics committee of Northwestern and Central Switzerland (EKNZ), 20/03/2017, ref: 2017-00250
2. Ministere de la Sante et de l'hygiene publique, comite national d'ethique de la recherche, 17 /04/2017, ref: 052/fMSHP/CNER-kp

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Study participants eligible for treatment will be randomly assigned to receive single, oral doses of placebo or ivermectin using a computer-generated stratified block randomization code. The random allocation sequence with varying random blocks will be provided by a statistician. The following doses of ivermectin will be used:

Adults: 0.2 µg/kg ivermectin
Preschoolers: 0.1 and 0.2 µg/kg ivermectin
School-aged children: 0.2, 0.4 and 0.6 µg/kg ivermectin

The treatment will be administered on one day only and 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)
Ivermectin

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

Key secondary outcome(s))
1. Egg reduction rate for Trichuris infection will be assessed using the quadruple Kato-Katz method at 21 days post-treatment

2. Cure rate and egg reduction rate for concomitant soil-transmitted helminth infections 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, 24, and 72 hours after treatment
4. Pharmacokinetic parameters: drug concentrations will be measured with a validated LC/MS method at baseline, 2, 4, 6, 7, 8, 9, 24, 48 and 72 hours post treatment

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Written informed consent signed by either participating PK patient or for the study involving children parents and/or caregiver; and oral assent by child (aged 6-12 years)
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. Corresponding age to be included in the respective age groups of interest (i.e. between 2 to 5 years for preschoolers, between 6 to 12 for school-aged children or ≥21 years for the adult age group sample)
5. Positive for T. trichiura eggs in the stool
6. Absence of major systemic illnesses, e.g. severe anemia, clinical malaria as assessed by a medical doctor, upon initial clinical assessment
7. No known or reported history of chronic illness as cancer, diabetes, chronic heart, liver or renal disease
8. No recent anthelminthic treatment (within past 4 weeks)
9. No known allergy to study medications (i.e., ivermectin)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. No written informed consent by individual/parents and/or caregiver
2. Presence of major systemic illnesses, e.g. 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 T. trichiura 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
Hôpital Méthodiste de Dabou
Dabou
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
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. 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

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	efficacy and safety results	28/09/2018		Yes	No
Results article	pharmacokinetics results	01/06/2019	13/03/2019	Yes	No