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Effect of de-worming on physical fitness of school-aged children in Yunnan, China

Submission date
14/09/2011

Recruitment status
No longer recruiting

Registration date
15/11/2011

Overall study status
Completed

Last Edited
17/09/2013

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims:
The most common parasitic worms that affect humans are the roundworm, whipworm and hookworm. Humans can be infected by eating food contaminated with the eggs of these parasitic worms or if the worms penetrate the skin. Parasitic worm infections can cause reduced growth rate (stunting) and wasting in school-aged children, and it is also possible that these parasitic worms reduce their physical fitness and strength.
The aim of this study is to determine whether de-worming has an effect on the physical fitness and strength of school-aged children in south-western Yunnan, China.

Who can participate?
Primary school children, aged 9-12 years, who are infected with one or more species of parasitic worms, but do not have major systemic illnesses.

What does the study involve?
The participants were subjected to tests to see if they are infected by parasitic worms, and were required to provide stool samples for analysis. Measurements of the participants weight, height and skinfolds were taken, as well as assessments on their performance in a 20m shuttle run, grip strength and standing broad jump tests. The participants randomly allocated to two groups to receive either albendazole or placebo (a dummy drug). The examinations were carried out before, during and after the participants were given treatment with albendazole or placebo.

What are the possible benefits and risks of participating?
Those in the albendazole group will no longer be infected with parasitic worms. Those who were not, would still benefit as all participants were given a single dose of albendazole free of charge at the end of the study. There were no known risks associated with taking part in this study.

Where is the study run from?
Rural primary schools in Menghai County, Xishuangbanna Dai, Yunnan province, China.

When is the study starting and how long is it expected to run for?
The study started in October 2011 and ran for approximately 8 months.

Who is funding the study?
Swiss Tropical and Public Health Institute, Switzerland.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of de-worming on physical fitness of school-aged children in Yunnan, China: a double-blind, randomised, placebo-controlled trial

Study objectives
De-worming can improve the physical fitness and strength of school-aged children

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Basel (Ethikkommission beider Basel) (EKBB, Switzerland; reference no. 144/11) approved on 9 May 2011 (original proposal) and 16 August 2011 (amendment)

2. Academic Board of the National Institute of Parasitic Diseases, Chinese Center for Disease Control and Prevention (IPD/China CDC) approved on 25 April 2011

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Soil-transmitted helminth infections

Interventions
Participants who were diagnosed with soil-transmitted helminths at the baseline parasitological examination will be randomly allocated to the following treatment arms:
Treatment arm 1: triple-dose albendazole (400 mg daily for 3 consecutive days)
Treatment arm 2: triple-dose placebo (single dose daily for 3 consecutive days)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in physical fitness and strength

Secondary outcome measures
1. Reduction of infection prevalence and intensity of soil-transmitted helminths and subsequent re-infection pattern
2. Changes in anthropometric and haemoglobin measurements

Overall study start date
17/10/2011

Completion date
25/06/2012

Eligibility

Key inclusion criteria
1. Primary school child, aged 9-12 years, male or female
2. Written informed consent by a parent / guardian on behalf of the child
3. Submission of two stool samples at baseline
4. Completion of anthropometric and haemoglobin measurements at baseline
5. Completion of 20 m shuttle run test at baseline
6. Completion of grip strength test and standing broad jump test at baseline
7. Infected with one or more common soil-transmitted helminths (Ascaris lumbricoides, Trichuris trichuria, hookworm)
8. Absence of major systemic illnesses, as assessed by a medical doctor at baseline
9. No known or reported drug allergy to albendazole
10. Treatment with albendazole (or matching placebo)
11. Anticipated residence in the study area for at least 1 year

Participant type(s)
Patient

Age group
Child

Lower age limit
9 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Children below the age of 9 years or above 12 years
2. No written informed consent
3. Less than 2 stool samples submitted at baseline
4. Presence of medical condition that prevents child from completing the physical fitness and strength tests
5. Known or reported drug allergy to albendazole
6. Absence/refusal of albendazole treatment (or matching placebo)
7. Attending other clinical trials during the study period

Date of first enrolment
17/10/2011

Date of final enrolment
25/06/2012

Locations

Countries of recruitment
China

Switzerland

Study participating centre
Department of Epidemiology and Public Health
Basel
Switzerland
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Sponsor information

Organisation
Swiss Tropical and Public Health Institute (Switzerland)

Sponsor details
Socinstrasse 57
Basel
Switzerland
4002

Sponsor type
Government

Website
http://www.swisstph.ch/

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Government

Funder Name
Swiss Tropical and Public Health Institute (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No