ISRCTN37143632 https://doi.org/10.1186/ISRCTN37143632

# Impact on physical fitness and cognitive ability in school children from southern Côte d'Ivoire after treatment against intestinal helminth infections

**Submission date**
25/10/2012

**Recruitment status**
No longer recruiting

**Registration date**
19/11/2012

**Overall study status**
Completed

**Last Edited**
14/05/2015

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Background and study aims
Millions of people in the developing world are at risk of parasitic diseases such as malaria and the so-called neglected tropical diseases (NTDs). The latter include, among others, parasitic worm (helminth) infections, such as soil-transmitted helminthiasis and schistosomiasis. There is a lack of studies investigating the effects of infection with multiple parasites (polyparasitism). Due to the long-lasting and un-specific nature of the symptoms, the public health burden can be greatly underestimated. Given that helminth and schistosomiasis infections cause malnutrition and anemia in school-aged children, it is also possible that they reduce their physical fitness, strength and school performance. The main aims of this study is to determine whether polyparasitic infections including soil-transmitted helminths and schistosomiasis have negative consequences on the physical fitness, strength and cognitive abilities of school-aged children in south-central Côte d'Ivoire, and if treatment against these diseases improves performance in infected children.

Who can participate?
All primary school children from grade 3-6 (age range: 8-15 years) will be invited to participate in this study.

What does the study involve?
The children will submit a stool, urine and finger-prick blood sample, and complete physical and cognitive tests and clinical examinations. All study participants will be treated against soil-transmitted helminths and schistosomiasis with a single dose of albendazole and praziquantel at the start of the study and 2 months and 5 months later. Further tests will take place at the end of the study follow-up, 7 months after the start of the study.

What are the possible benefits and risks of participating?
All participating children will benefit from repeated de-worming with albendazole and praziquantel free of charge. Both treatments are shown to be highly effective against the

common soil-transmitted helminths and schistosomiasis, respectively, and have good safety profiles. Treatment will also be offered for children with malaria or severely anaemia.

Where is the study run from?
The study will be conducted in a rural primary school in Agboville department, Agnéby region, Côte d'Ivoire.

When is the study starting and how long is it expected to run for?
The study will start in November 2012 and will run for about 7 months.

Who is funding the study?
Swiss National Science Foundation (SNSF).

Who is the main contact?
Prof. Dr Jürg Utzinger
juerg.utzinger@unibas.ch

# Contact information

### Type(s)
Scientific

### Contact name
Prof Juerg Utzinger

### Contact details
Swiss Tropical and Public Health Institute
Socinstrasse 57
Basel
Switzerland
4002

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Impact on physical fitness and cognitive ability in school children from southern Côte d'Ivoire after treatment against soil-transmitted helminths and schistosomiasis

### Study objectives

Treatment against soil-transmitted helminths and schistosomiasis can improve the physical fitness, strength and school performance of school-aged children.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Ethikkommission beider Basel, Switzerland, 14/04/2011, ref: 30/11 (amendment, 21/06/2011)
2. Comité National d'Ethique et de la Recherche, Côte d'Ivoire, 03/01/2011, ref: 09-2011/MSHP /CNER-P

## Study design
Intervention study with cross-sectional assessment

## Primary study design
Interventional

## Secondary study design
Cross-section survey

## 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
Neglected tropical diseases (soil-transmitted helminth and schistosomiasis infections) and malaria

## Interventions
All participants of the study will be treated against soil-transmitted helminths and schistosomiasis with a single dose of albendazole (400 mg) and praziquantel (40 mg/kg), respectively, at baseline, 2 month, 5 months and 7 months (follow-up assessment) after launch of the study.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Albendazole, praziquantel

## Primary outcome measure

Differences (non-infected vs. infected) and changes (before and after treatment) in physical fitness, strength and cognitive ability

### Secondary outcome measures
1. Reduction of infection prevalence and intensity of soil-transmitted helminths and schistosomiasis
2. Differences and changes in disease-related morbidity measures (malnutrition, anemia, organomegaly)

### Overall study start date
01/11/2012

### Completion date
01/06/2013

## Eligibility

### Key inclusion criteria
1. Primary school child, aged 8-15 years, male or female
2. Written informed consent by a parent/guardian on behalf of the child
3. Submission of 1 urine, 1 stool and 1 finger-prick blood sample at baseline
4. Completion of clinical, 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. Completion of cognitive testing
8. Absence of difficult health condition (clinical malaria, severe anemia, respiratory disease or other major illnesses) as assessed by a medical doctor at baseline
9. No known or reported drug allergy to albendazole or praziquantel
10. Treatment with albendazole and praziquantel

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
8 Years

### Upper age limit
15 Years

### Sex
Both

### Target number of participants
Approximately 300

### Key exclusion criteria

1. Children below the age of 8 years or above 15 years
2. No written informed consent
3. No complete set of urine, stool and blood sample 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 or praziquantel
6. Absence/refusal of albendazole and/or praziquantel treatment
7. Attending other clinical trials during the study period

### Date of first enrolment
01/11/2012

### Date of final enrolment
01/06/2013

## Locations

### Countries of recruitment
Côte d'Ivoire

Switzerland

### Study participating centre
**Swiss Tropical and Public Health Institute**
Basel
Switzerland
4002

## Sponsor information

### Organisation
Swiss Tropical and Public Health Institute (Switzerland)

### Sponsor details
Socinstrasse 57
Basel
Switzerland
4002

### Sponsor type
Research organisation

### Website
http://www.swisstph.ch/

**ROR**
https://ror.org/03adhka07

# Funder(s)

**Funder type**
Government

**Funder Name**
Swiss National Science Foundation [SNSF] (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