

Deworming and Health Education: A project to address intestinal worms in rural Guizhou province

Submission date 09/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/04/2013	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Our team's 2010 survey of poor, rural areas of Guizhou Province found rates of infection with soil transmitted helminths (STHs) to be around 40%. But Chinese government officials are not convinced that STH infection poses any real problem to Chinese schoolchildren. The goal of this study is to see whether an intensive campaign to reduce STH infection has any impact on child health or cognitive performance.

Who can participate?

Our sample will include both school-aged (9-11 years) and preschool-aged (3-5 years) children in the sample villages.

What does the study involve?

The study will have one intervention group and one control group with no intervention. The intervention involves administration of two rounds of albendazole treatment for all village children over age 3 years, health education training for both children and their parents, and an invitation to a health training session led by a local Centers for Disease Control and Prevention (CDC) official.

What are the possible benefits and risks of participating?

All children participating in the study will be dewormed (children in the control group will be dewormed at the conclusion of the endline survey), and families in the intervention group will also have the opportunity to learn about the dangers of STH infection and ways to prevent it. The risks of participating in the study are minimal - albendazole is safe with minimal side effects, mainly limited to mild stomach cramps as the STHs die and are expelled from the host body.

Where is the study run from?

110 villages in poor parts of rural Guizhou Province.

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

The study will begin in May, 2013, and will continue for 12 months until May, 2014.

Who is funding the study?

The study is funded by grants from the International Initiative for Impact Evaluation (3ie), the UBS Optimus Foundation, and Stanford University.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Deworming and Health Education: A cluster-randomized single-blind controlled trial to address soil-transmitted helminths in rural Guizhou province

Study objectives

The goal of this study is to see whether an intensive campaign to reduce STH infection has any impact on child health or cognitive performance.

This project involves treatment of children with soil-transmitted helminth infection (Ascaris, hookworm, Trichuris). Depending on the number of worms harbored, infection with parasitic intestinal worms can cause a range of symptoms, including diarrhea, general sickness and weakness, impaired cognitive development, stunted growth, and chronic intestinal blood loss.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval was provided by the Stanford University Human Subjects Research Institutional Review Board on the 15th September 2012 (ref: 25027)

Study design

Interventional cluster-randomised single-blind controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Soil-transmitted helminth infection

Interventions

Villagers in the intervention group will participate in the following activities:

1. All village children over age 3 years will be administered two 400 mg tablets of albendazole: one tablet at the start of the project, and another one after 6 months. The local CDC (with help of the village doctor) will be responsible for medication distribution and administration.
2. All parents of sampled children will receive one-on-one health education training from a trained project team member.
3. All school-aged children in our sample will receive health education training from a trained project team member
4. All parents of children in the village will be invited to a health training session led by a local CDC official with the help of the village doctor.

Villagers in the control group will not participate in any study interventions (no treatment).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Albendazole

Primary outcome measure

1. Soil-transmitted helminths (STH) infection rate, measured by a Kato-Katz smear test
2. Child height and weight
3. Student academic performance, measured by performance on a standardized Trends in International Mathematics and Science Study (TIMSS) test
4. Educational readiness for preschool-aged children, measured by performance on a standardized test of educational readiness
5. Cognitive processing, as measured by performance on a test of executive function

Measured at baseline and at end line (12 months after baseline).

Secondary outcome measures

1. Hemoglobin levels, measured by HemoCue 201+ technology
2. Worm burden [eggs per gram (epg)]

Measured at baseline and at endline (12 months after baseline).

Overall study start date

21/04/2013

Completion date

21/04/2014

Eligibility**Key inclusion criteria**

All school-aged (9-11 years) and preschool-aged (3-5 years) children living in our sample villages in poor parts of rural Guizhou Province will be included in the study.

Participant type(s)

Patient

Age group

Child

Lower age limit

9 Years

Upper age limit

11 Years

Sex

Both

Target number of participants

3300 children

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

21/04/2013

Date of final enrolment

21/04/2014

Locations

Countries of recruitment

China

United States of America

Study participating centre

616 Serra Street

Stanford

United States of America

94305

Sponsor information

Organisation

Stanford University (USA)

Sponsor details

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Encina Hall East, 5th floor

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United States of America

94305

Sponsor type

University/education

Website

<http://www.stanford.edu/>

ROR

<https://ror.org/00f54p054>

Funder(s)

Funder type

Charity

Funder Name

International Initiative for Impact Evaluation (3ie) (USA)

Funder Name

UBS Optimus Foundation

Funder Name

Stanford University Global Underdevelopment Action Fund (USA)

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