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# Efficacy of albendazole in treatment of Clonorchis sinensis infection

**Submission date**
19/02/2025

**Recruitment status**
No longer recruiting

**Registration date**
27/02/2025

**Overall study status**
Completed

**Last Edited**
25/02/2025

**Condition category**
Infections and Infestations

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

## Plain English summary of protocol

Background and study aims
This study focuses on a liver fluke called Clonorchis sinensis, which causes a disease known as clonorchiasis. Over 13 million people in China, South Korea, northern Vietnam, and far eastern Russia are infected. Currently, there is no vaccine, so treatment relies on a drug called praziquantel. However, there are concerns about drug resistance and side effects. This study aims to test another drug, albendazole, to see if it is effective and has fewer side effects.

Who can participate?
Adults aged 18-70 years who have been confirmed to be infected with Clonorchis sinensis can participate. The study will include 100 people, with 50 having a light infection and 50 having a moderate to heavy infection.

What does the study involve?
Participants will be randomly assigned to receive either praziquantel or albendazole. Those in the praziquantel group will take the drug three times a day for one day. Those in the albendazole group will take the drug twice a day for four days.

What are the possible benefits and risks of participating?
Participants may benefit from receiving treatment for their infection. However, there are risks of side effects from the drugs. Praziquantel is known to have higher rates of side effects, while albendazole is thought to have fewer side effects, but this is still being studied.

Where is the study run from?
National Institute of Parasitic Diseases, Chinese Center for Disease Control and Prevention (Chinese Center For Tropical Disease Research), China.

When is the study starting and how long is it expected to run for?
November 2024 to June 2025.

Who is funding the study?
National Disease Control and Prevention Administration, China.

Who is the main contact?
Dr Men-Bao Qian, qianmb@nipd.chinacdc.cn

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
2024-009

# Study information

### Scientific Title
Comparison on the efficacy of praziquantel and albendazole in treatment of Clonorchis sinensis infection

### Study objectives
High dose of albendazole is comparable to praziquantel in treatment of Clonorchis sinensis infection

### Ethics approval required
Ethics approval required

### Ethics approval(s)

Approved 20/11/2024, Ethical Review Committee of National Institute of Parasitic Diseases, Chinese Center for Disease Control and Prevention (Chinese Center For Tropical Disease Research) (No. 207, Rui Jin Er Road, Shanghai, 200025, China; +86-21-54593271; lizhen@nipd.chinacdc.cn), ref: 2024-009

## Study design
Randomized exploratory open-label phase II trial with two treatment arms

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

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

## Health condition(s) or problem(s) studied
Clonorchis sinensis infection

## Interventions
Light infection (Eggs per gram of feces <1 000):
Group 1: albendazole with a dose of 400 mg, twice a day for 4 days
Group 2: praziquantel (25 mg/kg 3 times a day for 1 day)

Moderate and heavy infection (Eggs per gram of feces ≥1 000):
Group 1: albendazole with a dose of 400 mg, twice a day for 4 days
Group 2: praziquantel (25 mg/kg 3 times a day for 1 day)

Randomisation by sealed envelope.

## Intervention Type
Drug

## Pharmaceutical study type(s)
Dose response

## Phase
Phase II

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

## Primary outcome measure

Cure rates and egg reduction rates three weeks after treatment: For diagnosis two stool samples will be collected before and after treatment. From each stool sample three Kato-Katz thick smears will be examined.

### Secondary outcome measures
Adverse events due to specific treatment: Participants will be monitored 3 hours and 24 hours after treatment with a standard questionnaire for adverse events.

### Overall study start date
20/11/2024

### Completion date
20/06/2025

## Eligibility

### Key inclusion criteria
1. Patients (18-70 years) infected with C. sinensis, as assessed by the presence of eggs in the stool
2. Signed written informed consent
3. Able and willing to be examined by a study physician at the beginning of the study and at the end of study follow-up survey (3-4 weeks post-treatment)
4. Able and willing to provide multiple stool samples at the beginning and end of study
5. Absence of major systemic illnesses, psychiatric and neurological disorders as assessed by the medical doctor, upon initial clinical assessment
6. No known or reported hypersensitivity to albendazole or praziquantel
7. No known or reported history of chronical illness as cancer, diabetes, chronic heart, liver or renal disease
8. For females, not pregnant, as assessed by a female nurse (interview and pregnancy test if need be), upon initial clinical assessment

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
Both

### Target number of participants
100

### Key exclusion criteria

1. For females, pregnancy
2. Presence of any abnormal medical condition, judged by the study physician
3. History of acute or severe chronic disease
4. Known or reported hypersensitivity to albendazole or praziquantel
5. Known or reported psychiatric or neurological disorders
6. Use of any anthelminthic within the past month
7. Attending other clinical trials during the study
8. Absence of signed written informed consent sheet

### Date of first enrolment
20/03/2025

### Date of final enrolment
20/05/2025

## Locations

### Countries of recruitment
China

### Study participating centre
**Binyang Center for Disease Control and Prevention**
No 12, Jianshe Community, Binzhou township, Binyang county
Nanning
China
530400

## Sponsor information

### Organisation
National Institute of Parasitic Diseases, Chinese Center for Disease Control and Prevention (Chinese Center For Tropical Disease Research)

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### Sponsor type
Other

# Funder(s)

**Funder type**
Government

**Funder Name**
National Disease Control and Prevention Administration

# Results and Publications

**Publication and dissemination plan**
Planned scientific publication in a peer reviewed journal.

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be available upon reasonable request from qianmb@nipd.chinacdc.cn

**IPD sharing plan summary**
Available on request