

Efficacy of albendazole in treatment of *Clonorchis sinensis* infection

Submission date 19/02/2025	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/02/2025	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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 $\geq 1\ 000$):

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

Phase

Phase II

Drug/device/biological/vaccine name(s)

albendazole, praziquantel

Primary outcome(s)

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.

Key secondary outcome(s)

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

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 chronic 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

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 anthelmintic 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)

Funder(s)

Funder type

Government

Funder Name

National Disease Control and Prevention Administration

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes