

A research study of the role of artesunate in the treatment of *Fasciola hepatica*

Submission date 16/03/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/03/2007	Overall study status Completed	☐ Protocol
Last Edited 21/03/2013	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
061330

Study information

Scientific Title
A randomised controlled pilot study of artesunate versus triclabendazole for the treatment of human fascioliasis in central Vietnam

Acronym

CE

Study objectives

The primary purpose of this protocol is to evaluate Artesunate as compared to Trichlorbendazole in the treatment of Fasciola hepatica with the hypothesis that Artesunate will improve the treatment of this disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethical and Scientific Committee of the Hospital for Tropical Diseases, Ho Chi Minh City (Viet Nam)

Primary study design

Interventional

Study design

Open label randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fasciola hepatica

Interventions

Group A will be treated using triclabendazole at the recommended dose of 20 mg/Kg body weight and given as two doses of 10 mg/Kg body weight after food with a time lapse of 12 hours between doses.

Group B will be treated using oral artesunate at a dose of 4 mg/kg body weight/day for ten days.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Artesunate, trichlorbendazole

Primary outcome(s)

Clinical improvement in presenting complaint.

Key secondary outcome(s)

1. Improvement in ultrasound appearance
2. Changes in eosinophilic count in peripheral blood
3. Biochemical parameters to return to normal

4. Haematology parameters return to normal
5. Absence of eggs in the stool

Completion date

30/03/2007

Eligibility

Key inclusion criteria

1. Either gender, aged greater than 8 years
2. Fasciola hepatica
3. Gives consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Does not meet with inclusion criteria

Date of first enrolment

01/07/2005

Date of final enrolment

30/03/2007

Locations

Countries of recruitment

Viet Nam

Study participating centre

Oxford University Clinical Research Unit

Ho Chi Minh City

Viet Nam

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Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 061330)

Results and Publications**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	01/03/2008		Yes	No