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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Open label randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 measure

Clinical improvement in presenting complaint.

Secondary outcome measures

- 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

Overall study start date

01/07/2005

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

Age group

Other

Sex

Both

Target number of participants

100

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)

Sponsor details

University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD
+44 (0)1865 270143
research.services@admin.ox.ac.uk

Sponsor type

University/education

Website

http://www.ox.ac.uk/

ROR

https://ror.org/052gg0110

Funder(s)

Funder type

Charity

Funder Name

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

Results and Publications

Publication and dissemination planNot 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2008		Yes	No