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

Submission date	Recruitment status	[_] Prospectively registered
16/03/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

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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
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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 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

Study outputs

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