

Artemether in the treatment of Fasciola hepatica and/or Fasciola gigantica infections in Egypt

Submission date 20/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/03/2009	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Jennifer Keiser

Contact details

Department of Medical Parasitology and Infection Biology
Swiss Tropical Institute
Basel
Switzerland
4054

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Artemether in the treatment of Fasciola hepatica and/or Fasciola gigantica infections in Egypt: an open-label non-randomised proof of concept trial

Acronym

AM-Fasciola

Study objectives

Artemether shows efficacy against Fasciola hepatica and/or Fasciola gigantica.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Switzerland: Ethics Committee of Basel(EKBB Ethikkommission beider Basel), approved on 12/03/2007 (ref: 54/07)
2. Egypt: Theodor Bilharz Research Institute Institutional Review Board, approved on 20/12/2006 (ref: FWA 000010609)

The study has also received an approval from the Ministry of Health and Population, Cairo.

Study design

Interventional open-label non-randomised proof of concept trial, consisting of 2 x single-arm studies

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Fascioliasis

Interventions

This trial consisted of two separate single-arm studies. Study 1 and 2 involved different subjects.

Study 1: 22 patients were given 80 mg artemether (oral) twice daily for 3 days

Study 2: 19 patients received 200 mg artemether (oral) three times within 24 hours (morning, lunch, evening) (duration of intervention: 1 day)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Artemether

Primary outcome measure

Cure rate and egg reduction rate at 28 days post treatment.

Secondary outcome measures

Adverse events. Patient were monitored for 3 hours after each dose.

Overall study start date

01/04/2007

Completion date

31/12/2008

Eligibility**Key inclusion criteria**

1. Both males and females, age 11-70 years
2. For married females, not pregnant, as assessed by the medical doctor last menstrual cycle, upon initial clinical assessment
3. Absence of major systemic illnesses, as assessed by the medical doctor, upon initial clinical assessment
4. Infection with *F. hepatica* and/or *F. gigantica* as confirmed by standard parasitological stool examination
5. No known or reported hypersensitivity to artemether
6. No known or reported history of chronic illness such as cancer, diabetes, hypertension, chronic heart, liver or renal disease
7. Full clinical examination
8. Written informed consent

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Presence of any abnormal medical condition, judged by the medical doctor. If several patients experience serious adverse events the study will be stopped.
2. Severe liver disease of other aetiology
3. Recent history of anthelmintic drugs (triclabendazole, albendazole, bithionol, dehydroemetine, praziquantel within past 4 weeks)
4. Attending other clinical trials during the study
5. For females: pregnancy, lactation

Date of first enrolment

01/04/2007

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Egypt

Switzerland

Study participating centre

Department of Medical Parasitology and Infection Biology

Basel

Switzerland

4054

Sponsor information

Organisation

Swiss Tropical Institute (Switzerland)

Sponsor details

o/c Prof Jennifer Keiser

Basel

Switzerland

4054

Sponsor type

Government

Website

<http://www.sti.ch/>

ROR

<https://ror.org/03adhka07>

Funder(s)

Funder type

Other

Funder Name

Velux Foundation (Velux Stiftung) (Switzerland)

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