ISRCTN10372301 https://doi.org/10.1186/ISRCTN10372301

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

Submission date	Recruitment status	[_] Prospectively registered
20/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/03/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/03/2009	Infections and Infestations	[_] 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

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 Ethikkomission 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

Study type(s)
Treatment

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(s)
Cure rate and egg reduction rate at 28 days post treatment.

Key secondary outcome(s))
Adverse events. Patient were monitored for 3 hours after each dose.

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 chronical illness such as cancer, diabetes, hypertension, chronic heart, liver or renal disease
7. Full clinical examination
8. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

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 anthelminthic 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)

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Other

Funder Name
Velux Foundation (Velux Stiftung) (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration