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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
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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 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

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 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

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 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)

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