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Tribendimidine in the treatment of liver fluke infection in China

Submission date	Recruitment status	[_] Prospectively registered
07/03/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/03/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/08/2013	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Clonorchiasis, a disease caused by the oriental liver fluke Clonorchis sinensis, is of considerable public health importance. The disease is constantly present in the Peoples Republic of China, Taiwan, Vietnam, and the Republic of Korea, where an estimated 601 million people are at risk and more than 35 million people are infected. There is currently no vaccine available for prevention of clonorchiasis and chemotherapy is the main treatment. However, chemotherapy of clonorchiasis relies on a single drug called praziquantel. Efforts are underway to administer praziquantel more widely, in preventive chemotherapy campaigns. There is some concern that this strategy might result in the development and spread of drug-resistant parasites. There is a need for discovery and development of new drugs. The aim of this study is to assess how well oral tribendimidine works in patients infected with C. sinensis.

Who can participate?
75 individuals with a parasitological-confirmed infection with C. sinensis

What does the study involve?
Patients will be randomly allocated to one of three groups:
- single oral dose of 400 mg tribendimidine
- oral doses of 400 mg tribendimidine daily for 3 days
- praziquantel (25 mg/kg 3 times a day) for 2 consecutive days

What are the possible benefits and risks of participating?
The two drugs which are compared are well known, widely used and have little adverse events. All children enrolled in the study will benefit from a treatment against liver fluke infection and soil transmitted helminths. All diagnosed parasitic infections will be treated according to national guidelines.

Where is the study run from?
Guangdong province, China.

When is study starting and how long is it expected to run for?
The study will last for 5-6 weeks and will take place in March/April 2012.

Who is funding the study?
The study will be funded by DFID/Wellcome Trust/MRC.

Who is the main contact?
Professor Jennifer Keiser

Contact information

Type(s)
Scientific

Contact name
Prof Jennifer Keiser

Contact details
Socinstr. 57
Basel
Switzerland
4051

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Tribendimidine in the treatment of Clonorchis sinensis infection in the Peoples Republic of China

Study objectives
Tribendimidine achieves a higher efficacy than praziquantel in the treatment of Clonorchis infections

Follow up to http://www.controlled-trials.com/ISRCTN23425032

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkomission Beider, Basel, 09 February 2012 ref: 375/11

Study design

Randomized exploratory open-label phase II trial with three treatment arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Liver fluke infections (Clonorchis sinesis)

Interventions
Group 1: single oral dose of 400 mg tribendimidine
Group 2: oral doses of 400 mg tribendimidine daily for 3 days
Group 3: praziquantel (25 mg/kg 3 times a day) for 2 consecutive days

Follow up is 21 days after treatment. Praziquantel brand names are Biltricide® and Cesol®.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Praziquantel, tribendimidine

Primary outcome measure
Cure rates and egg reduction rates three weeks after treatment:
For diagnosis three stool samples will be collected before and after treatment. From each stool sample three Kato-Katz thick smears will be examined. Additionally 1g of stool will be preserved for later diagnosis with the ether concentration method.

Secondary outcome measures
Adverse events due to specific treatment:
Participants will be monitored 3 hours after treatment. 24 hours after each day of treatment they will be asked with a standard questionnaire for adverse events.

Overall study start date
10/03/2012

Completion date
10/05/2012

Eligibility

Key inclusion criteria
1. Patients (adults aged ≥18 years) infected with C. sinensis, as assessed by the presence of eggs in the stool
2. Signed written informed consent
3. Able and willing to be examined by a study physician at the beginning of the study and at the end-of study follow-up survey (3 - 4 weeks post-treatment)
4. Able and willing to provide multiple stool samples at the beginning and end of study
5. Absence of major systemic illnesses, psychiatric and neurological disorders as assessed by the medical doctor, upon initial clinical assessment
6. No known or reported hypersensitivity to tribendimidine or praziquantel
7. No known or reported history of chronical illness as cancer, diabetes, chronic heart, liver or renal disease
8. For females, not pregnant in the first trimester, as assessed by a female nurse (interview and pregnancy test if need be), upon initial clinical assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

Key exclusion criteria
1. For females, pregnancy in first trimester
2. Presence of any abnormal medical condition, judged by the study physician
3. History of acute or severe chronic disease
4. Known or reported hypersensitivity to tribendimidine or praziquantel
5. Known or reported psychiatric or neurological disorders
6. Use of any anthelmintic within the past month
7. Attending other clinical trials during the study
8. Absence of signed written informed consent sheet

Date of first enrolment
10/03/2012

Date of final enrolment
10/05/2012

Locations

Countries of recruitment
China

Switzerland

Study participating centre
Socinstr. 57
Basel
Switzerland
4051

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
One Kemble Street
London
United Kingdom
WC2B 4AN

Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

Funder Name
Department For International Development [DFID] (UK)

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust (UK) ref: G1100699

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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	01/04/2013		Yes	No