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Levamisole hydrochloride as adjunctive therapy in severe falciparum malaria with high parasitaemia

Submission date 24/05/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/05/2006	**Overall study status** Completed	
Last Edited 17/12/2013	**Condition category** 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
077166/Z/05/Z

Study information

Scientific Title

Study objectives
Cytoadherence of parasitised erythrocytes to microvascular endothelium is the pathological hallmark of falciparum malaria. In-vitro studies show that levamisole, a specific alkaline-phosphatase inhibitor, decreases adhesion of parasitised erythrocytes to CD36. A pilot study in uncomplicated malaria indicates that this happens in-vivo.

Please note that as of 29/07/2010 this record has been updated to incorporate protocol changes; all changes can be found in the relevant section with the above update date. At this time, please note that this trial is not recruiting in India, therefore this country of recruitment has been removed. Also, the target sample size and anticipated end date have also been updated; this initial information at the time of registration was as follows:
Initial target number of participants: 40
Initial anticipated end date: 01/09/2007

All other changes can be found in the relevant field.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 17/02/2009: Oxford Tropical Research Ethics Committee gave approval on the 1st June 06 (ref: 007-06)

Study design
Multicentre, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Severe falciparum malaria with high parasitaemia

Interventions

Current information as of 29/07/2010;
Patient admitted with severe falciparum malaria and peripheral blood parasitaemia more than or equal to 2% will be randomised to either adjunctive treatment with a single dose of 150 mg oral levamisole hydrochloride, or no adjunctive treatment. Anti-malarial treatment will be intravenous artesunate.

Initial information at time of registration:
Patient admitted with severe falciparum malaria and peripheral blood parasitaemia more than or equal to 5% will be randomised to either adjunctive treatment with a single dose of 150 mg oral levamisole hydrochloride, or no adjunctive treatment. Anti-malarial treatment will be intravenous artesunate.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Levamisole hydrochloride, artesunate

Primary outcome measure
Sequential assessment of peripheral blood parasitaemia and parasite stages. If sequestration is indeed reduced by levamisole, an initial increase in peripheral parasitaemia, and an increase in the number of late stages in the peripheral blood smear can be expected.

Secondary outcome measures
1. Microvascular flow measured using orthogonal polarisation spectral imaging
2. Lactate clearance time

Overall study start date
22/05/2006

Completion date
30/08/2010

Eligibility

Key inclusion criteria
Current information as of 29/07/2010:
1. The patient or attending relative, able and willing to give informed consent. The proposed consent form and information sheets are attached and will be translated into the local language.
2. Severe falciparum malaria
3. Peripheral blood parasitaemia more than or equal to 2%
4. Patients aged 16 to 65 years old, both genders
5. No contraindications to levamisole, or artesunate therapy, such as documented allergies to either of the drugs

Initial information at time of registration:
1. The patient or attending relative, able and willing to give informed consent. The proposed

consent form and information sheets are attached and will be translated into the local language.
2. Severe falciparum malaria
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4. Patients aged 16 to 65 years old, both genders
5. No contraindications to levamisole, or artesunate therapy, such as documented allergies to either of the drugs

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Current information as of 29/07/2010:
1. Patient or relatives unable or unwilling to give informed consent
2. More than one dose of previous antimalarial treatment within one week of admission
3. Pregnancy or breastfeeding

Initial information at time of registration:
1. Patient or relatives unable or unwilling to give informed consent
2. Previous antimalarial treatment within one week of admission
3. Pregnancy

Date of first enrolment
22/05/2006

Date of final enrolment
30/08/2010

Locations

Countries of recruitment
Bangladesh

Thailand

Study participating centre
Mahidol University
Bangkok
Thailand
10400

Sponsor information

Organisation
University of Oxford (United Kingdom)

Sponsor details
Centre for Clinical Vaccinology and Tropical Medicine
Churchill Hospital
Old Road
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Oxford
England
United Kingdom
OX3 7LJ
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Sponsor type
University/education

Website
http://www.jr2.ox.ac.uk/ndm/Tropical_Medicine

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 077166)

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	01/01/2014		Yes	No