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Levamisole hydrochloride as adjunctive therapy in falciparum malaria

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/10/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/02/2009	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
077166

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. This pilot study aims to examine whether this happens in vivo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Tropical Research Ethics Committee gave approval on the 1st June 2006 (ref: 007-06)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Falciparum malaria

Interventions
Patients admitted to Mae Sot Hospital with uncomplicated falciparum malaria will be randomised to either adjunctive treatment with a single dose of 150 mg oral levamisole hydrochloride, or no adjunctive treatment. Antimalarial treatment will be oral quinine and doxycycline.

Peripheral blood parasitaemia and parasite stages will be assessed frequently. If sequestration of parasitised erythrocytes is reduced, an initial increase in peripheral blood parasitaemia and appearance of more mature parasites in the peripheral blood can be expected.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Levamisole hydrochloride, quinine and doxycycline

Primary outcome measure
Sequential assessment of peripheral blood parasitaemia and parasite stages.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2003

Completion date
01/10/2006

Eligibility

Key inclusion criteria
1. The patient or attending relative is able and willing to give informed consent - the proposed consent form and information sheets are attached and will be translated into Burmese
2. Uncomplicated falciparum malaria
3. Patients aged 16 to 65 years old, either sex
4. No contraindications to levamisole, quinine or doxycycline therapy, like documented allergies to any of the drugs

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 (as of 01/10/2006 21 patients were recruited)

Key exclusion criteria
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
01/10/2003

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
Thailand

Study participating centre
Wellcome Unit
Bangkok
Thailand
10400

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
CCVTM
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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