

Levamisole hydrochloride as adjunctive therapy in falciparum malaria

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 14/10/2005	Overall study status Completed	☐ Protocol
Last Edited 04/02/2009	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number
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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Sequential assessment of peripheral blood parasitaemia and parasite stages.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration