

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

Registration date

24/05/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

17/12/2013

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Arjen Dondorp

Contact details

Mahidol University

Wellcome Unit

Faculty of Tropical Medicine

420/6 Rajvithi Road

Bangkok

Thailand

10400

Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Multicentre, randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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:

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Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014		Yes	No