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Randomised comparison of chloroquine plus sulfadoxine-pyrimethamine versus artesunate plus mefloquine versus artemether-lumefantrine in the treatment of uncomplicated falciparum malaria in the Lao People's Democratic Republic

Submission date 22/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/07/2005	**Overall study status** Completed	
Last Edited 06/02/2015	**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
065146

Study information

Scientific Title
Randomised comparison of chloroquine plus sulfadoxine-pyrimethamine versus artesunate plus mefloquine versus artemether-lumefantrine in the treatment of uncomplicated falciparum malaria in the Lao People's Democratic Republic

Study objectives
Randomised comparison of chloroquine plus sulfadoxine-pyrimethamine versus artesunate plus mefloquine versus artemether-lumefantrine in the treatment of uncomplicated falciparum malaria in the Lao People's Democratic Republic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
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
Malaria

Interventions
A randomised comparison of three oral antimalarial combinations.
1. Chloroquine plus sulfadoxine-pyrimethamine
2. Artesunate plus mefloquine
3. Artemether-lumefantrine

42-day follow-up period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Chloroquine, sulfadoxine-pyrimethamine, artesunate, mefloquine, artemether-lumefantrine

Primary outcome measure
Parasitological and clinical responses to treatment.

Secondary outcome measures
1. Parasite and fever clearance times
2. Gametocytaemia
3. Changes in haematocrit following antimalarial treatment

Overall study start date
14/07/2002

Completion date
17/10/2003

Eligibility

Key inclusion criteria
1. Patients or their guardians gave fully informed written consent
2. Had a density of asexual P. falciparum of 5000 to 200,000 per microlitre of blood
3. Were aged more than one year
4. Had an axillary temperature of more than 37.5°C or history of fever in the previous three days
5. Were likely to stay in the hospital until parasite clearance and complete the 42-day follow up period

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
330

Key exclusion criteria

1. Pregnant or lactating women
2. Patients who took a full course of any antimalarials in the previous three days
3. Patients with signs of severe malaria
4. Those with history of allergy or contraindication to the study drugs

Date of first enrolment
14/07/2002

Date of final enrolment
17/10/2003

Locations

Countries of recruitment
Lao People's Democratic Republic

Study participating centre
Mahosot Hospital
Vientiane
Lao People's Democratic Republic
PO Box 5

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD

Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

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	15/10/2004		Yes	No