

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	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/02/2015	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Parasitological and clinical responses to treatment.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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)

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

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