

# 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

<b>Submission date</b> 22/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/02/2015	<b>Condition category</b> 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

**Contact name**  
Dr Mayfong Mayxay

**Contact details**  
Mahosot Hospital  
Microbiology Laboratory  
Mahosot Road  
Vientiane  
Lao People's Democratic Republic  
PO Box 5  
+856 (0)21 250752  
Mayfong@tropmedres.ac

## 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?
<a href="#">Results article</a>	Results	15/10/2004		Yes	No