# 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	Recruitment status	Prospectively registered		
22/07/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/07/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
06/02/2015	Infections and Infestations			

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

Protocol serial number

# 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

## 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

Αll

#### 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