

# Clinical and laboratory assessment of antimalarial drug efficacy in Lao PDR: an open, randomised comparison of artesunate plus mefloquine versus dihydroartemisinin-piperaquine (Artekin) for 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

**Registration date**  
22/07/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
11/03/2013

**Condition category**  
Infections and Infestations

☐ Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

065146

## **Study information**

**Scientific Title**

### **Study objectives**

An open, randomised comparison of artesunate plus mefloquine versus dihydroartemisinin-piperaquine (Artekin) for 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**

Uncomplicated falciparum malaria

### **Interventions**

1. Oral Artesunate-Mefloquine (AM)
2. Dihydroartemisinin-piperaquine (Artekin)

### **Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Artesunate, mefloquine, and dihydroartemisinin-piperaquine (Artekin)

**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**

20/05/2004

**Completion date**

20/09/2004

## **Eligibility**

**Key inclusion criteria**

1. Patients or their guardians gave fully informed written consent
2. Had a density of asexual *P. falciparum* of 1000 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**

Not Specified

**Sex**

Both

**Target number of participants**

220

**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**

20/05/2004

**Date of final enrolment**

20/09/2004

## **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**

Research organisation

**Funder Name**

The Western Pacific Regional Office of the World Health Organisation (Philippines)

**Funder Name**

The Wellcome Trust (UK) (grant ref: 065146)

## 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	01/08/2006		Yes	No