

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

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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(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

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

Healthy volunteers allowed

No

Age group

Not Specified

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

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)

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

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	01/08/2006		Yes	No