ISRCTN32978789 https://doi.org/10.1186/ISRCTN32978789

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

Registration date
22/07/2005

Overall study status
Completed

Last Edited
11/03/2013

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Results article	results	01/08/2006		Yes	No