

Is there any evidence of antimalarial resistance to artemisinin derivatives in southern Laos?

Submission date
21/05/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
24/06/2010

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
24/06/2010

Condition category
Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Study information

Scientific Title

Clinical investigation of in-vivo susceptibility of Plasmodium falciparum to artesunate in Xepon Inter-District Hospital, Savannakhet Province, Laos

Acronym

Anredaud

Study objectives

The parasite clearance times (PCT) and the efficacy after 2 mg/kg and 4 mg/kg oral artesunate, followed by 3-days artemether-lumefantrine, are not prolonged.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Oxford Tropical Research Ethics Committee (UK) approved on the 8th June 2009 (ref: OXTREC 29-09)
2. Lao PDR National Ethics Committee for Health Research (NECHR) approved on the 18th May 2009 (Ref: 246/NECHR)

Primary study design

Interventional

Study design

Open randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Plasmodium falciparum malaria, antimalarial drugs

Interventions

Treatment arm 1: oral artesunate 2 mg/kg/day for 3 days followed by oral artemether-lumefantrine (20/120 mg): 1 dose twice daily for three days. Dosing by body weight will be: 1 tablet if less than 15 kg, 2 tablets if 15 - 24 kg, 3 tablets if 25 - 34 kg, and 4 tablets if greater than 35 kg.

Treatment arm 2: oral artesunate 4 mg/kg/day for 3 days followed by oral artemether-lumefantrine (20/120 mg): 1 dose twice daily for three days. Dosing by body weight will be: 1 tablet if less than 15 kg, 2 tablets if 15 - 24 kg, 3 tablets if 25 - 34 kg, and 4 tablets if greater than 35 kg.

The duration of follow-up for both arms is 42 days.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Artesunate, artemether-lumefantrine

Primary outcome(s)

Number of patients with PCT greater than 72 hours. If six or more patients per treatment group (n = 20) have PCTs greater than 72 hours the trial will be stopped.

Key secondary outcome(s)

To assess the efficacy of artesunate 2 mg/kg/day and 4 mg/kg/day followed by 3-days artemether-lumefantrine in the treatment of uncomplicated *P. falciparum* malaria after 42-days follow up. Assessed on the basis of an assessment of the parasitological and clinical outcome of antimalarial treatment according to the latest WHO guidelines.

Completion date

01/10/2010

Eligibility

Key inclusion criteria

1. Male and female, aged greater than 10 years
2. Female patients between ages of 10 and 12 years old, provided they have not reached menarche, and those who have passed through the menopause
3. Mono-infection with *P. falciparum* as detected by microscopy
4. Parasitaemia of 10,000 - 175,000/μl asexual forms
5. Presence of axillary or tympanic temperature greater than or equal to 37.5°C or oral or rectal temperature of greater than or equal to 38°C or history of fever during the past 24 hours
6. Ability to swallow oral medication
7. Ability and willingness to comply with the study protocol for the duration of the study and to comply with the study visit schedule
8. Informed consent from the patient or from a parent or guardian in the case of children

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Presence of general danger signs or severe *falciparum* malaria according to the definitions of the World Health Organization (WHO, 2000)
2. Mixed or mono-infection with another *Plasmodium* species detected by microscopy
3. Presence of severe malnutrition (defined as a child whose growth standard is below -3 z-score, has symmetrical oedema involving at least the feet or has a mid-upper arm circumference less than 110 mm)
4. Presence of febrile conditions due to diseases other than malaria or other known underlying chronic or severe diseases
5. Regular medication, which may interfere with antimalarial pharmacokinetics
6. Received antimalarial drugs in the previous 48 hours
7. History of hypersensitivity reactions or contraindications to any of the medicine(s) used
8. Female patients of child-bearing age, defined as those who menstruate or are aged over 12 years and have not reached the menopause
9. Breastfeeding
10. Splenectomy

Date of first enrolment

01/06/2010

Date of final enrolment

01/10/2010

Locations

Countries of recruitment

Lao People's Democratic Republic

Study participating centre**Microbiology Laboratory**

Vientiane Capital

Lao People's Democratic Republic

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Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Research organisation

Funder Name

World Health Organization (WHO) (Switzerland)

Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type

Government organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary