

The efficacy of chloroquine in treatment of vivax malaria in southern Laos

Submission date 22/01/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 23/01/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 02/02/2009	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

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Additional identifiers

Protocol serial number
LMC-11

Study information

Scientific Title
An assessment of the efficacy of oral chloroquine for the treatment of uncomplicated Plasmodium vivax malaria in Savannakhet Province, Lao People's Democratic Republic (PDR)

Acronym

LVT

Study objectives

That oral chloroquine remains efficacious in the treatment of Plasmodium vivax malaria in southern Laos.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. Oxford Tropical Research Ethics Committee (OXTREC) (UK) on the 24th May 2005
2. National Ethic Committee for Health Research (NECHR) (Lao PDR) on the 24th May 2005

Primary study design

Interventional

Study design

A pilot single arm efficacy study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Vivax malaria

Interventions

Oral chloroquine 25 mg base/kg over 3 days (10 mg base/kg stat, followed by 10 mg base/kg at 24 hours later, followed by 5 mg base/kg at 48 hours).

Total duration of follow-up is 42 days.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Chloroquine

Primary outcome(s)

Cure rate.

Outcomes measured daily until parasite clearance and then weekly until 42 days post treatment.

Key secondary outcome(s)

1. Parasite clearance time
2. Fever clearance time

Outcomes measured daily until parasite clearance and then weekly until 42 days post treatment.

Completion date

30/12/2010

Eligibility

Key inclusion criteria

1. Written informed consent from patient or attending relative
2. Age greater than 1 year old, either sex
3. *P. vivax* infection (greater than 500 asexual stages/ μ L)
4. Acute uncomplicated malaria (World Health Organization [WHO] 2000)
5. Axillary temperature greater than 37.5°C
6. No full course of antimalarial treatment in the previous 3 days
7. High probability that patient will be able to complete 42 days follow up

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Inability or unwillingness to give informed consent
2. Mixed species malaria infections
3. Severe malaria (WHO, 2000)
4. History of allergy to chloroquine
5. Asymptomatic malaria
6. Low probability of 42 days follow up

Date of first enrolment

01/06/2005

Date of final enrolment

30/12/2010

Locations

Countries of recruitment

Lao People's Democratic Republic

Study participating centre

Microbiology Laboratory
Vientiane
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
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 066828)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration