ISRCTN17027907 https://doi.org/10.1186/ISRCTN17027907

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

Submission date	Recruitment status	[_] Prospectively registered
22/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2009	Infections and Infestations	[_] 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

Study design
A pilot single arm efficacy study

Primary study design
Interventional

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/µL)
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