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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 measure
Cure rate.

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

Secondary outcome measures
1. Parasite clearance time
2. Fever clearance time

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

Overall study start date
01/06/2005

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

Age group
Other

Sex
Both

Target number of participants
100

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)

Sponsor details
Centre for Clinical Vaccinology and Tropical Medicine (CCVTM)
Churchill Hospital
Oxford
England
United Kingdom
OX3 7LJ
research.services@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ccvtm.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

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

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