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Radical cure of vivax malaria

Submission date	Recruitment status	[_] Prospectively registered
12/11/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/11/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2017	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Malaria is a serious tropical disease spread by mosquitoes. It can be prevented and treated using antimalarial medication, but it often comes back again after treatment. These relapses can be prevented only by the drug primaquine, but there is uncertainty about how long primaquine should be given for. The aim of this study is to compare two widely recommended ways of giving primaquine, a short course and a long course, to see which is better at preventing relapse.

Who can participate?
Patients age over 3 with malaria

What does the study involve?
Participants are randomly allocated to one of three groups. The first group is treated with chloroquine only for 3 days. The second group is treated with chloroquine followed by primaquine for 5 days. The third group is treated with chloroquine followed by primaquine for 14 days. Malaria relapse rate and side effects are assessed in all three groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Mahidol University (Thailand)

When is the study starting and how long is it expected to run for?
April 2003 to September 2004

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Prof. Nicholas White
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CP1

Study information

Scientific Title
Open label comparison of Chloroquine (CQ) alone versus CQ plus 5 days unobserved Primaquine or CQ plus 14 days unobserved primaquine

Acronym
CqPq

Study objectives
Radical cure of vivax malaria requires 14 days primaquine. However, a 5-day regimen has been widely recommended. This trial compares the two radical regimens versus no primaquine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Calcultta School of Tropical Medicine, 2003
2. Faculty of Tropical Medicne, Mahidol University, 08/12/2005, ref: TM-IRB056/2005

Study design
Open-label randomised comparison

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vivax malaria

Interventions
1. Chloroquine (25mg base/kg total) only ; 10mg/kg on day 1, 10mg/kg on day 2 then 5mg/kg on day 3
2. Chloroquine (25mg base/kg total as above) followed by primaquine 0.25mg base/kg/day for 5 days-total dose 1.25mg base/kg (75mg in an adult)
3. Chloroquine (25mg base/kg total) followed by primaquine 0.25mg base/kg/ day for 14 days - total dose 3.5mg base/kg (210mg in an adult)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Chloroquine, primaquine

Primary outcome(s)
Relapse rate

Key secondary outcome(s))
Adverse effects

Completion date
01/09/2004

Eligibility

Key inclusion criteria
1. Age > 3 years
2. Fully informed consent to long follow-up
3. Acute uncomplicated vivax malaria
4. Not pregnant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria

1. <3 years
2. Pregnancy
3. Severe disease

Date of first enrolment
01/04/2003

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
India

Thailand

Study participating centre
Mahidol University
Bangkok
Thailand
10400

Sponsor information

Organisation
Mahidol University (Thailand)

ROR
https://ror.org/01znkr924

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) (reference No. 066439/2/01/2)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

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	01/05/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes