

Radical cure of vivax malaria

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

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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Contact details

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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. Calcutta School of Tropical Medicine, 2003
2. Faculty of Tropical Medicine, Mahidol University, 08/12/2005, ref: TM-IRB056/2005

Primary study design

Interventional

Study design

Open-label randomised comparison

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