

Does thiamin treatment reduce the incidence of adverse effects during treatment of falciparum malaria?

Submission date 21/01/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 23/01/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/07/2014	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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-18

Study information

Scientific Title
Thiamin treatment and Plasmodium falciparum malaria in Laos

Acronym

TIP

Study objectives

The frequency of adverse events after antimalarial therapy will be significantly lower in those who receive thiamin supplementation in comparison to those who do not.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. Oxford Tropical Research Ethics Committee (UK) on the 21st August 2007 (ref: OXTREC 026-07)
2. Lao PDR National Ethics Committee for Health Research (NECHR) on the 18th July 2007

Study design

An exploratory, double-blind, parallel group, placebo-controlled trial, randomised (variable blocks), superiority trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria, beriberi

Interventions

Treatment arm:

Oral thiamin (5 mg tablet) two tablets immediately after antimalarial drugs, followed by two tablets daily for 7 days followed by one tablet daily until day 42.

Placebo arm:

Physically identical placebo containing no thiamin.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Thiamin

Primary outcome(s)

To determine whether the frequency of adverse events, after antimalarial therapy, are significantly lower in those who receive thiamin supplementation in comparison to those who do not.

For the primary endpoint the outcome measure will be assessed clinically before treatment and on each day until discharge and then on days 7, 14, 21, 28, 38 and 42 after start of treatment.

Key secondary outcome(s)

To determine the frequency of biochemical thiamin deficiency and whether this is related to the clinical severity of disease and the extent of resolution of deficiency between those who do and do not receive thiamin supplementation.

The secondary outcome measures will be assessed by red cell transketolase assays of washed red cell samples on day 0 and 42.

Completion date

01/12/2011

Eligibility

Key inclusion criteria

1. Written fully informed consent given by patients and in the case of children, by parents or guardians
2. Males and females of any age
3. Microscopically confirmed *Plasmodium falciparum* infection with history of fever. Multiple *Plasmodium* species infections will be included.
4. Willingness and ability to comply with the study protocol for the duration of the 42 days follow up
5. Did not take a full course of any antimalarial drugs in previous three days

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Known hypersensitivity to thiamin
2. Presence of intercurrent non-malarial illness or any condition which in the judgement of the investigator would place the subject at undue risk or interfere with the results of the study
3. Clinically apparent suspected thiamin deficiency (beriberi), which will be defined (World Health Organization [WHO] 1999) as:
 - 3.1. Children less than 5 years: peripheral oedema or clinical evidence for pulmonary oedema, or cyanosis or classical hoarse cry
 - 3.2. Adults and children greater than 5 years: peripheral oedema or clinical evidence for pulmonary oedema or lower limb paraesthesia or, before malarial illness, difficulty in rising from squatting position (it will be difficult to distinguish features of wet beriberi, such as peripheral and pulmonary oedema, from consequences of malaria, such as severe anaemia, acute

respiratory distress syndrome [ARDS] and pneumonia. Clinicians will be cautious and classify the patient as having beriberi if there is doubt).

Date of first enrolment

01/06/2008

Date of final enrolment

01/12/2011

Locations

Countries of recruitment

Lao People's Democratic Republic

Study participating centre

Microbiology Laboratory

Vientiane

Lao People's Democratic Republic

100

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/06/2012		Yes	No
Results article	results	15/07/2014		Yes	No