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

Submission date	Recruitment status	[X] Prospectively registered
21/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/07/2014	Infections and Infestations	

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-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

Secondary study design
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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2008

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

Age group
Other

Sex
Both

Target number of participants
814

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)

Sponsor details
Churchill Hospital
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Sponsor type
University/education

Website
http://www.jr2.ox.ac.uk/ndm/Tropical_Medicine

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

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