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Is there any evidence of antimalarial resistance to artemisinin derivatives in southern Laos?

Submission date	Recruitment status	[_] Prospectively registered
21/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/06/2010	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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100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Clinical investigation of in-vivo susceptibility of Plasmodium falciparum to artesunate in Xepon Inter-District Hospital, Savannakhet Province, Laos

Acronym
Anredaud

Study objectives
The parasite clearance times (PCT) and the efficacy after 2 mg/kg and 4 mg/kg oral artesunate, followed by 3-days artemether-lumefantrine, are not prolonged.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Oxford Tropical Research Ethics Committee (UK) approved on the 8th June 2009 (ref: OXTREC 29-09)
2. Lao PDR National Ethics Committee for Health Research (NECHR) approved on the 18th May 2009 (Ref: 246/NECHR)

Study design
Open randomised controlled 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
Plasmodium falciparum malaria, antimalarial drugs

Interventions
Treatment arm 1: oral artesunate 2 mg/kg/day for 3 days followed by oral artemether-lumefantrine (20/120 mg): 1 dose twice daily for three days. Dosing by body weight will be: 1 tablet if less than 15 kg, 2 tablets if 15 - 24 kg, 3 tablets if 25 - 34 kg, and 4 tablets if greater than 35 kg.
Treatment arm 2: oral artesunate 4 mg/kg/day for 3 days followed by oral artemether-lumefantrine (20/120 mg): 1 dose twice daily for three days. Dosing by body weight will be: 1 tablet if less than 15 kg, 2 tablets if 15 - 24 kg, 3 tablets if 25 - 34 kg, and 4 tablets if greater than 35 kg.

The duration of follow-up for both arms is 42 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artesunate, artemether-lumefantrine

Primary outcome measure
Number of patients with PCT greater than 72 hours. If six or more patients per treatment group (n = 20) have PCTs greater than 72 hours the trial will be stopped.

Secondary outcome measures
To assess the efficacy of artesunate 2 mg/kg/day and 4 mg/kg/day followed by 3-days artemether-lumefantrine in the treatment of uncomplicated P. falciparum malaria after 42-days follow up. Assessed on the basis of an assessment of the parasitological and clinical outcome of antimalarial treatment according to the latest WHO guidelines.

Overall study start date
01/06/2010

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Male and female, aged greater than 10 years
2. Female patients between ages of 10 and 12 years old, provided they have not reached menarche, and those who have passed through the menopause
3. Mono-infection with P. falciparum as detected by microscopy
4. Parasitaemia of 10,000 - 175,000/µl asexual forms
5. Presence of axillary or tympanic temperature greater than or equal to 37.5°C or oral or rectal temperature of greater than or equal to 38°C or history of fever during the past 24 hours
6. Ability to swallow oral medication
7. Ability and willingness to comply with the study protocol for the duration of the study and to comply with the study visit schedule
8. Informed consent from the patient or from a parent or guardian in the case of children

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Presence of general danger signs or severe falciparum malaria according to the definitions of the World Health Organization (WHO, 2000)
2. Mixed or mono-infection with another Plasmodium species detected by microscopy
3. Presence of severe malnutrition (defined as a child whose growth standard is below -3 z-score, has symmetrical oedema involving at least the feet or has a mid-upper arm circumference less than 110 mm)
4. Presence of febrile conditions due to diseases other than malaria or other known underlying chronic or severe diseases
5. Regular medication, which may interfere with antimalarial pharmacokinetics
6. Received antimalarial drugs in the previous 48 hours
7. History of hypersensitivity reactions or contraindications to any of the medicine(s) used
8. Female patients of child-bearing age, defined as those who menstruate or are aged over 12 years and have not reached the menopause
9. Breastfeeding
10. Splenectomy

Date of first enrolment
01/06/2010

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Lao People's Democratic Republic

Study participating centre
Microbiology Laboratory
Vientiane Captial
Lao People's Democratic Republic
100

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Churchill Hospital
CCVTM

Headington
Oxford
England
United Kingdom
OX3 7LJ

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO) (Switzerland)

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

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