ISRCTN08391109 https://doi.org/10.1186/ISRCTN08391109

Efficacy of artemether-lumefantrine treatment in uncomplicated malaria (Plasmodium falciparum) patients and in-vitro experiment on susceptibility of malaria (P. falciparum) strains to new chemical substances

Submission date 18/06/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/06/2009	**Overall study status** Completed	
Last Edited 11/05/2010	**Condition category** 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
N/A

Study information

Scientific Title
Susceptibility of Plasmodium falciparum from Southern Laos to artemether-lumefantrine and new chemical entities: in-vivo and in-vitro studies in the province of Attapeu, Laos

Acronym
SPfL

Study objectives
Malaria parasite (P. falciparum) of southern Laos is susceptible to artemether-lumefantrine (in vivo) and also to new chemical entities (in-vitro).

As of 11/05/2010 this record was updated to include an extended anticipated end date; the intial anticipated end date at the time of registration was 31/12/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Kanton of Basel (Ethikkommission beider Basel) approved on the 21st April 2009 (ref: 131/09)

Study design
Unblinded, single-arm efficacy trial

Primary study design
Interventional

Secondary study design
Non 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
Uncomplicated P. falciparum malaria infection

Interventions
All subjects will receive treatment with artemether-lumefantrine (standard protocol). Patients will be followed up daily until day 7 and then weekly until 42 days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Artemether-lumefantrine

Primary outcome measure
Parasite clearance time, assessed daily after until day 7

Secondary outcome measures
1. Early treatment failure, measured by malaria symptoms present on day 3 after treatment start
2. Late treatment failure, measured by malaria symptoms on any follow-up after day 7
3. Late parasitological failure, measured by parasite present on any follow-up after day 7

Overall study start date
06/07/2009

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Male or female aged greater than 1 year
2. Fever (axillary, 37.5°C) on admission, or reported history of fever within the last 72 hours (3 days)
3. Willingness to participate in particular to stay at the hospital for the first 7 days
4. Full written informed consent (signed) provided by themselves or by attending relatives
5. Signed pre-consent if patient was referred from a district hospital or dispensary
6. Willing to stay under close medical supervision at the hospital for the study duration of at 7 days, and willingness to participate weekly until the 6th week (42 days follow-up)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
110

Key exclusion criteria
1. Pregnancy: all females (aged 12 - 50 years) are required to have a "negative" pregnancy test (urine) or are currently using an acceptable method of contraception
2. Lactating mother
3. Intake of anti-malarial drugs for the last 3 days (reported on admission, urine samples for confirmation)
4. Mixed malaria infection on admission, i.e. P. falciparum and any other Plasmodium species
5. A previous history of intolerance or hypersensitivity to the study drugs artemether-lumefantrine or to drugs with similar chemical structures, such as artemether, artemisinin or dihydroartemisinin and lumefantrine-like compounds
6. History of significant cardiovascular, liver or renal functional abnormality or any other clinically significant illness
7. Symptoms of severe vomiting
8. Signs or symptoms of severe malaria (World Health Organization [WHO] 2003)
9. Unable to follow the protocol
10. Age of 12 months and below

Date of first enrolment
06/07/2009

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
Lao People's Democratic Republic

Switzerland

Study participating centre
Swiss Tropical Institute
Basel
Switzerland
4002

Sponsor information

Organisation
Medicines for Malaria Venture (MMV) (Switzerland)

Sponsor details
PO Box 1826
20, rte de Pré-Bois
Geneva 15

Switzerland
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Sponsor type
Research organisation

Website
http://www.mmv.org

ROR
https://ror.org/00p9jf779

Funder(s)

Funder type
Research organisation

Funder Name
Medicines for Malaria Venture (MMV) (Switzerland)

Alternative Name(s)
MMV

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit 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