

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	☒ Prospectively registered
		☐ Protocol
Registration date 30/06/2009	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 11/05/2010	Condition category Infections and Infestations	☐ Individual participant data
		☐ 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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Contact details

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Additional identifiers

Protocol serial number

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 initial 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

Study type(s)

Treatment

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(s)

Parasite clearance time, assessed daily after until day 7

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration