

# 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

<b>Submission date</b> 18/06/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/05/2010	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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## 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 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

### 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  
1215  
+41 (0)22 799 4060  
info@mmv.org

**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