# A comparison of the efficacy and effectiveness of dihydroartemisinin-piperaquine and artesunate-mefloquine in the treatment of falciparum malaria

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
24/12/2005		☐ Protocol	
Registration date 24/04/2006	Overall study status Completed	Statistical analysis plan	
		[X] Results	
<b>Last Edited</b> 06/08/2007	Condition category Infections and Infestations	Individual participant data	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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## Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

#### Study objectives

Non-inferiority of efficacy and effectiveness of dihydroartemisinin-piperaquine compared to mefloquine-artesunate for the treatment of uncomplicated falciparum malaria in adults and children in western Myanmar.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved by Doctors Without Borders (Medecins sans Frontieres [MSF]) Ethical Review Board on 05/12/2003

#### Study design

An open randomised comparison

#### Primary study design

Interventional

## Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Falciparum malaria

#### **Interventions**

Comparison of two different treatment regimes: dihydroartemisinin-piperaquine and mefloquine-artesunate. Both treatment regimes were given observed or not observed; total of four study groups.

## Intervention Type

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Dihydroartemisinin-piperaquine and artesunate-mefloquine

#### Primary outcome(s)

Polymerase chain reaction (PCR) adjusted parasitological failure rates by day 42

## Key secondary outcome(s))

- 1. Vivax appearances
- 2. Gametocytaemia (person gametocyte weeks between day 0 and 42)
- 3. Whole blood piperaguine levels at day 7
- 4. Adverse effects

#### Completion date

# **Eligibility**

#### Key inclusion criteria

- 1. Patients with fever (axillary temperature >37.5°C), or a history of fever within 48 hours
- 2. Confirmed falciparum malaria (mixed infection P. falciparum with P. vivax and/or P. malariae were included), with more than 500 but less than 100,000 asexual parasites per ml

#### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Signs of severe and complicated malaria
- 2. Children below one-year-old
- 3. Pregnant women
- 4. Patients with a history of taking mefloquine during the previous two months
- 5. Patients taken any other antimalarial drugs in the previous 48 hours
- 6. Patients with a history of psychiatric diseases

#### Date of first enrolment

08/12/2003

#### Date of final enrolment

30/03/2004

## Locations

#### Countries of recruitment

Myanmar

#### Study participating centre Thanlwin Road 62 A

Yangon Myanmar

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# Sponsor information

#### Organisation

Doctors Without Borders (Medecins sans Frontieres [MSF]) (The Netherlands)

#### **ROR**

https://ror.org/04237en35

# Funder(s)

## Funder type

Charity

#### **Funder Name**

Internally funded by Doctors Without Borders (Artsen zonder Grenzen MSF) (Holland)

## **Results and Publications**

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	24/06/2006		Yes	No