

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

Submission date 24/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/08/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design

Interventional

Study design

An open randomised comparison

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 piperaquine levels at day 7
4. Adverse effects

Completion date

30/03/2004

Eligibility

Key inclusion criteria

1. Patients with fever (axillary temperature $>37.5^{\circ}\text{C}$), 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