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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

Registration date
24/04/2006

Overall study status
Completed

Last Edited
06/08/2007

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
08/12/2003

Completion date
30/03/2004

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

Age group
Adult

Sex
Both

Target number of participants
640

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)

Sponsor details
Plantage Middenlaan 14
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Netherlands
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Sponsor type
Charity

Website
http://www.artsenzondergrenzen.nl

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	24/06/2006		Yes	No