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A randomised open label trial to assess the efficacy, safety, and pharmacokinetic parameters of a fixed dose formulation of artesunate-mefloquine and standard dose artesunate and mefloquine as loose tablets for treatment of uncomplicated falciparum malaria (Thailand)

Submission date
08/04/2005

Registration date
07/06/2005

Last Edited
05/04/2017

Recruitment status
No longer recruiting

Overall study status
Completed

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

Protocol serial number
RPC075

Study information

Scientific Title
A randomised open label trial to assess the efficacy, safety, and pharmacokinetic parameters of a fixed dose formulation of artesunate-mefloquine and standard dose artesunate and mefloquine as loose tablets for treatment of uncomplicated falciparum malaria (Thailand)

Study objectives
To assess the efficacy, safety, and pharmacokinetic parameters of a fixed dose formulation of artesunate-mefloquine and standard dose artesunate and mefloquine as loose tablets for treatment of uncomplicated falciparum malaria in Thailand.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current information as of 01/12/2009:
The study was approved by two ethics committees:
1. The Faculty of Tropical Medicine Ethical Committee, Mahidol University, Thailand
2. The World Health Organization Secretariat Committee on Research Involving Human Subjects

Initial information at time of registration:
The study was approved by three ethics committees:
1. The Faculty of Tropical Medicine Ethical Committee, Mahidol University, Thailand
2. The Oxford Tropical Research Ethics Committee
3. The World Health Organization Secretariat Committee on Research Involving Human Subjects

Primary study design
Interventional

Study design
Randomised open-label trial

Study type(s)
Treatment

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

Interventions
Fixed dose combination (Intervention):
Artesunate/mefloquine fixed dose combination of artesunate 100 mg and mefloquine 200 mg tablets

Non fixed tablets/standard dose (Control):
Mefloquine 250 mg and artesunate 50 mg as loose tablets on standard weight based regimen

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artesunate-mefloquine, artesunate, mefloquine

Primary outcome(s)
Current information as of 01/12/2009:
Pharmacokinetic parameters of both drug regimens.

Initial information at time of registration:
Day 63 PCR-adjusted cure rates of each treatment calculated using KaplanMeier survival analysis with log rank test for significance.

Key secondary outcome(s)
Current information as of 01/12/2009:
1. Time to fever
2. Time to parasite clearance
3. PCR corrected, day 28 cure rate

Safety and tolerability endpoints:
1. Adverse events

Initial information at time of registration:
1. Time to fever
2. Time to parasite clearance
3. Rates of appearance of vivax malaria during follow-up

Safety and tolerability endpoints:
1. Incidence of anaemia
2. Other adverse events

Completion date
11/07/2005

Eligibility

Key inclusion criteria
1. Age 18 to 65 years
2. Body weight at least 40 kg
3. Microscopically confirmed, monoinfection of P. falciparum (parasitaemia more than 2/200 White Blood Cell count [WBC]). Note: if vivax parasitaemia is detected after Day 0, patients will still be kept in the study and follow the schedule of investigations.
4. History of fever or presence of fever (axillary temperature more than 37.5°C)
5. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant or lactating women
2. P. falciparum asexual stage parasitaemia more than 4% red blood cells (175,000/µl)
3. Clinical and/or lab features of severe malaria:
3.1. Impaired consciousness
3.2. Inability to eat and drink
3.3. Vomiting more than two episodes in preceeding 24 hours
3.4. Convulsions during present illness
3.5. Prostration
3.6. Severe anaemia (haematocrit [Hct] less than 20%)
3.7. Respiratory distress/pulmonary oedema
3.8. Shock
3.9. Spontaneous bleeding
3.10. Acute haemolysis with haemoglobinuria
3.11. Acute renal failure
3.12. Hyperbilirubinaemia (more than 3 mg/dL)
3.13. Hypoglycaemia
3.14. Acidosis
4. Baseline electrocardiogram (ECG) abnormality
5. Recent ingestion of mefloquine within previous 60 days
6. Contraindications to mefloquine
7. History of convulsions and/or psychiatric illnesses
8. Known hypersensitivity to artemisinins or mefloquine
9. Splenectomy

Date of first enrolment
02/12/2004

Date of final enrolment
11/07/2005

Locations

Countries of recruitment
Switzerland

Thailand

Study participating centre

20, Avenue Appia
Geneva -27
Switzerland
CH 1211

Sponsor information

Organisation
Drugs for Neglected Diseases initiative (DNDi) (Switzerland)

ROR
https://ror.org/022mz6y25

Funder(s)

Funder type
Research organisation

Funder Name
Drugs for Neglected Diseases initiative (DNDi) (Switzerland)

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP) /World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2010		Yes	No