

Pharmacokinetics and efficacy of dihydroartemisinin-piperaquine in the treatment of uncomplicated falciparum malaria in children in Burkina Faso

Submission date 11/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 05/02/2008	Overall study status Completed	☐ Protocol
Last Edited 13/05/2015	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ 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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Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Assessing the efficacy of Dihydroartemisinin-piperaquine in African patients suffering of uncomplicated falciparum malaria and to determine the pharmacokinetics profile of piperaquine in children 2 - 10 years old presenting falciparum malaria

Study objectives

Preliminary results of pharmacokinetic (PK) studies indicate that the disposition of piperaquine is altered in children compared to adults.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Institut de Recherche en Science de la Sante/Centre Muraz (IRSS/CM) (Burkina Faso) , 26/07/2007, ref: 005-2007/CE-CM
2. University of California, San Francisco (USCF) committee on Human Research, 27/07/2007, ref: # H40380-31179-01

Study design

1. Treatment efficacy: open-label trial
2. Population kinetic studies will use sparse capillary sampling

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions

Patients are given dihydroartemisinin piperaquine once daily for three days. Treatment is weight based and directly observed by the study nurse. The follow up duration is 42 days.

The study is a one arm study but there is a randomisation to determine the groups where the patient will be included for the PK purpose.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dihydroartemisinin-piperaquine

Primary outcome(s)

1. Determination of the pharmacokinetic profile of piperaquine in children with uncomplicated falciparum malaria
2. Assess the efficacy of dihydroartemisinin piperaquine

Key secondary outcome(s)

1. Risk of recurrent malaria*
2. Risk of clinical and parasitological treatment failure*
3. Prevalence of fever (defined as both subjective fever in the previous 24 hours and measured axillary temperature greater than 37.5°C) on follow-up days 1, 2, and 3
4. Prevalence of parasitaemia on follow-up days 2 and 3
5. Change in mean haemoglobin from day 0 to 42 (or day of rescue therapy for patients classified as late clinical failure [LCF] or late parasitological failure [LPF])
6. Prevalence of gametocytaemia on follow-up days 2, 3, 7, 14, 21 and 28
7. Change in the prevalence of molecular markers possibly associated with drug resistance on day 0 or the day of recurrent parasitaemia, including polymorphisms in *Plasmodium falciparum* chloroquine resistance transporter (Pfcr1) and *Plasmodium falciparum* multidrug-resistance (Pfmdr1) genes
8. In vitro sensitivity to antimalarial drugs

*Risks will be estimated using the Kaplan-Meier product limit formula based on a modified intention-to-treat analysis.

Completion date

31/01/2008

Eligibility

Key inclusion criteria

On day 0, patients with symptoms suggestive of malaria and a positive screening thick blood smear will be assessed for the following selection criteria by study physicians for appropriate care:

1. Not previously enrolled in this study
2. Aged greater than 6 months
3. Weight greater than 5 kg
4. Fever (greater than 37.5°C axillary) or history of fever in the previous 24 hours
5. Absence of any history of serious side effects to study medications
6. No evidence of a concomitant febrile illness in addition to malaria
7. Provision of informed consent and ability to participate in 42-day follow-up (patient has easy access to health unit)
8. No history of antimalarial use in the previous two weeks (except for chloroquine)
9. No danger signs or evidence of severe malaria defined as:
 - 9.1. Unarousable coma (if after convulsion, greater than 30 minutes)
 - 9.2. Recent febrile convulsions (within 24 hours)
 - 9.3. Altered consciousness (confusion, delirium, psychosis, coma)
 - 9.4. Lethargy
 - 9.5. Unable to drink or breast feed
 - 9.6. Vomiting everything
 - 9.7. Unable to stand/sit due to weakness
 - 9.8. Severe anaemia (haemoglobin [Hb] less than 5.0 gm/dL)
 - 9.9. Respiratory distress (laboured breathing at rest)
 - 9.10. Jaundice

After going to the laboratory, the subjects will be referred to the study nurse for treatment allocation and treatment with the study medications. Patients must also meet the following

criterion:

10. Absence of repeated vomiting of study medications on day 0

Patients will return to the clinic on day 1 and will be excluded from the study if the following inclusion criteria are not met:

11. Plasmodium falciparum mono-infection

12. Parasite density 2000 - 200,000/ul

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Sex

All

Key exclusion criteria

1. Inability to participate in 42 days follow up

2. Pregnant women

3. Severe malaria

Date of first enrolment

06/08/2007

Date of final enrolment

31/01/2008

Locations

Countries of recruitment

Burkina Faso

Thailand

Study participating centre

Shoklo Malaria Research Unit (SMRU)

Mae Sot

Thailand

63110

Sponsor information

Organisation

Beijing Holley-Cotec Pharmaceuticals Co. Ltd (China)

Funder(s)

Funder type

Charity

Funder Name

Doris Duke Charitable Foundation (USA)

Alternative Name(s)

Doris Duke Charitable Foundation, Inc., DDCF Trust, Doris Duke Foundation, The Doris Duke Charitable Foundation, DDCF, DDF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Beijing Holley-Cotec Pharmaceuticals Co. Ltd (China)

Funder Name

National Budget of Institut de Recherche en Science de la Sante (IRSS) (Burkina Faso)

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	18/08/2014		Yes	No