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Comparison of Artemether-Lumefantrine and Dihydroartemisinin-Piperaquine for treatment of uncomplicated malaria in Uganda: evaluation of efficacy, safety, and tolerability

Submission date
06/07/2006

Recruitment status
No longer recruiting

Registration date
17/08/2006

Overall study status
Completed

Last Edited
25/10/2022

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
Version 1.1

Study information

Scientific Title
Comparison of Artemether-Lumefantrine and Dihydroartemisinin-Piperaquine for treatment of uncomplicated malaria in Uganda: evaluation of efficacy, safety, and tolerability

Acronym
AL vs DP efficacy and safety trial

Study objectives
To compare the efficacy, safety, and tolerability of Artemether-Lumefantrine (AL) and Dihydroartemisinin-Piperaquine (DP) for the treatment of uncomplicated falciparum malaria in Uganda.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ugandan National Council of Science and Technology (HS 112; February 14 2006)
2. University of California San Francisco Committee for Human Research (H9926-28076-01; January 11 2006)
3. Makerere University Faculty of Medicine Research and Ethics Committee (January 31 2006).

Study design
Randomised, single-blinded trial of two leading new antimalarial regimens at three sites with varying transmission intensity.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malaria (P.falciparum)

Interventions
Subjects will be randomised to treatment with AL or DP. Subjects in the DP arm will also receive placebo tablets to ensure that the number of doses received is identical in the two treatment groups.
Subjects who fail initial therapy will receive quinine, the standard treatment for recurrent malaria in Uganda.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Artemether-lumefantrine and dihydroartemisinin-piperaquine

Primary outcome(s)

Risk of treatment failure unadjusted and adjusted by genotyping at day 42

Key secondary outcome(s))
1. Prevalence of fever on days one to three
2. Prevalence of parasitemia on days two and three
3. Change in mean hemoglobin level between days zero and 42 (or day of treatment failure)
4. Prevalence of gametocytes during follow-up
5. Risk of serious adverse events during follow-up
6. Risk of adverse events of moderate or greater severity, at least possibly related to the study medications, excluding patients requiring quinine therapy
7. Selection of molecular markers associated with drug resistance

Completion date
20/07/2006

Eligibility

Key inclusion criteria
1. Aged six months to ten years
2. Weight more than 5 kg
3. Fever (more than 37.5°C axillary) or history of fever in the previous 24 hours
4. Provision of informed consent and agreement to follow-up for 42 days
5. Plasmodium falciparum mono-infection
6. Parasite density more than 2000/µl and less than 200,000/µl

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
10 years

Sex
All

Key exclusion criteria
1. Previously enrolled in this study
2. History of serious side effects to study medications
3. Evidence of a concomitant febrile illness
4. Evidence of severe malaria or danger signs
5. Repeated vomiting of study medications on day zero

Date of first enrolment
20/03/2006

Date of final enrolment
20/07/2006

Locations

Countries of recruitment
Uganda

United States of America

Study participating centre
University of California, San Francisco (UCSF)
San Francisco
United States of America
CA 94143

Sponsor information

Organisation
Uganda Malaria Surveillance Project (Uganda)

Funder(s)

Funder type
Government

Funder Name
Centers for Disease Control and Prevention/Global Malaria Prevention and Control Cooperative agreement number U50/CCU925112-01

Funder Name
Department for International Development (DFID) through Malaria Consortium (SUBK0001)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		11/06/2008		Yes	No
Other publications		18/05/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes