

Uganda Malaria Surveillance Project - Comparison of amodiaquine plus artesunate and artemether-lumefantrine for treatment of uncomplicated malaria in Uganda: evaluation of efficacy, safety, and tolerability

Submission date 04/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/10/2009	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

Acronym

UMSP

Study objectives

To compare the efficacy, safety, and tolerability of amodiaquine + artesunate and artemether + lumefantrine for the treatment of uncomplicated falciparum malaria in Uganda.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ugandan National Council of Science and Technology, University of California San Francisco Committee for Human Research, University of California Berkeley IRB

Study design

Randomised single-blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions

Subjects will be randomized to treatment with amodiaquine + artesunate (AQ + AS) or artemether + lumefantrine (AL). Subjects in the AQ + AS arm will also receive placebo tablets to ensure that the number of doses received is identical in the two treatment groups. Subjects requiring repeat therapy (second-line therapy given for symptomatic malaria) will receive quinine.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Amodiaquine + artesunate and artemether + lumefantrine

Primary outcome(s)

Primary outcome will be based on the risk of clinical rescue therapy. Pairwise comparisons between regimens will be made based on a per-protocol analysis.

Key secondary outcome(s))

1. Risk of clinical treatment failure
2. Risk of parasitological rescue therapy
3. Risk of parasitological treatment failure
4. Risk of fever during the first 3 days of follow-up: presence or absence of objective fever (axillary temperature $>37.5^{\circ}\text{C}$) or patient report of fever on days 1, 2, 3
5. Risk of parasitemia on follow-up days 2 and 3: proportion of positive versus negative thick blood smears on day 2 and day 3
6. Change in mean haemoglobin from day 0 to 28 or day of repeat therapy
7. Proportion of subjects lacking gametocytes on day 0 with gametocytaemia on any follow-up day
8. Risk of serious adverse events: proportion of patients experiencing any serious adverse event in each treatment group during the 28-day follow-up period, excluding treatment failures
9. Risk of adverse events of moderate or greater severity, at least possibly related to the study medications, excluding treatment failures

Completion date

14/07/2005

Eligibility

Key inclusion criteria

1. Age 1-10 years
2. Weight $>10\text{ kg}$
3. Fever ($>37.5^{\circ}\text{C}$ axillary) or history of fever in the previous 24 hours
4. Provision of informed consent and agreement to follow-up for 28 days
5. *P. falciparum* mono-infection
6. Parasite density $>2000/\mu\text{l}$ and $<200,000/\mu\text{l}$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 years

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 0

Date of first enrolment

14/12/2004

Date of final enrolment

14/07/2005

Locations

Countries of recruitment

Uganda

Study participating centre

Institute Of Public Health

Kampala

Uganda

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Sponsor information

Organisation

Uganda Malaria Surveillance Project

Funder(s)

Funder type

Government

Funder Name

Centers for Disease Control and Prevention/Association of Schools of Public Health cooperative agreement, 'Malaria Surveillance and Control in Uganda' (SA3569 and S1932-21/21), and the Department for International Development (DFID)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration