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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	Recruitment status	[_] Prospectively registered
04/11/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/11/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/10/2009	Infections and Infestations	[_] Record updated in last year

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

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

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
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 measure
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.

Secondary outcome measures
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 °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

Overall study start date
14/12/2004

Completion date
14/07/2005

Eligibility

Key inclusion criteria
1. Age 1-10 years
2. Weight >10 kg
3. Fever (>37.5 °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/µl and <200,000/µl

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
400

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

Sponsor details

P.O. Box 7475
Kampala
Uganda
7475

Sponsor type
Other

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

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