

Uganda Malaria Surveillance Project - Combination therapies for treatment of uncomplicated falciparum malaria in Uganda: evaluation of efficacy, safety, and tolerability

Submission date 26/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/04/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym

UMSP

Study objectives

To assess the efficacy, safety and tolerability of alternative antimalarial therapies for treatment of uncomplicated falciparum malaria as they compare to Chloroquine/Sulfadoxine-Pyrimethamine (CQ/SP) treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics information provided at time of registration.

Study design

Single-blind, randomized clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Malaria

Interventions

Chloroquine + sulfadoxine-pyrimethamine versus amodiaquine + sulfadoxine-pyrimethamine
versuss amodiaquine + artesunate

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Alternative therapies to chloroquine/sulfadoxine-pyrimethamine (CQ/SP)

Primary outcome measure

1. 28-day risks for any recurrent infection
2. Recrudescence
3. New infections.

Secondary outcome measures

1. Risk of recurrent infection unadjusted by genotyping at day 14
2. Presence of fever on days one to three
3. Parasitemia on days two and three
4. Change in haemoglobin level between the day of enrolment and the last day of follow-up
5. Presence of gametocytes during any follow-up day
6. Incidence of adverse events

Overall study start date

01/11/2002

Completion date

31/05/2004

Eligibility**Key inclusion criteria**

1. Aged over six months
2. Fever (more than 37.5 °C axillary) or history of fever in the previous 24 hours
3. Absence of any history of serious side effects to study medications, including allergy to sulfa drugs
4. No evidence of severe malaria or danger signs
5. No evidence of a concomitant febrile illness
6. *P. falciparum* mono-infection
7. Parasite density more than 2000/ul and less than 200,000/ul
8. Agreement to return for all scheduled follow-up visits
9. Provision of informed consent
10. No history of anti-folate or amodiaquine use in past seven days
11. Absence of pregnancy

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Sex

Not Specified

Target number of participants

2160

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2002

Date of final enrolment

31/05/2004

Locations**Countries of recruitment**

Uganda

United States of America

Study participating centre

University of California

Berkeley

United States of America

94720-7360

Sponsor information**Organisation**

Uganda Malaria Surveillance Project (Uganda)

Sponsor details

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Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/07/2005		Yes	No