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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

Registration date
10/05/2005

Last Edited
22/04/2008

Recruitment status
No longer recruiting

Overall study status
Completed

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

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
P.O. Box 7475
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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Financial support was provided by the Centers for Disease Control/Association of Schools of Public Health cooperative agreement, Malaria Surveillance and Control in Uganda (SA3569 & 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

Study outputs

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