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Evaluation of the best approach to retreating recurrent malaria in Ugandan children

Submission date	Recruitment status	[_] Prospectively registered
30/11/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2013	Infections and Infestations	

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
1.2

Study information

Scientific Title
Comparison of quinine, artemether lumefantrine and dihydroartemisinin piperaquine for retreatment of recurrent malaria in Ugandan children

Study objectives
There is no difference in the efficacy and safety of quinine and two artemisinin-based combination therapies (ACTs) (artemether lumefantrine [AL] and dihydroartemisinin piperaquine [DP]) for treatment of recurrent uncomplicated malaria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Makerere University Faculty of Medicine Research and Ethics Committee on 5th October 2007
2. The Uganda National Council of Science and Technology on 9th November 2007 (ref: HS 362)

Study design
Nested phase IV, randomised, single blinded, multi-arm clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Malaria

Interventions
The patients will be randomised to either quinine or another ACT regimen:
1. AL to quinine or DP
2. Chlorproguanil hydrochloride-dapsone-artesunate [CDA] to quinine
3. AL or DP
4. DP to quinine or AL

Patients are then followed for 28 days to assess their response to therapy.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Artemether-lumefantrine (AL), dihydroartemisinin-piperaquine (DP), quinine, chlorproguanil hydrochloride-dapsone-artesunate (CDA)

Primary outcome measure
1. Polymerase chain reaction (PCR) unadjusted treatment failure up to day 28
2. PCR adjusted treatment failure up to day 28

Secondary outcome measures
1. Fever clearance time
2. Asexual parasite clearance time
3. Gametocytaemia (prevalence and density) at day 7, 14, 21 and 28 after treatment
4. Haemoglobin (Hb) changes day 28 or day of treatment failure
5. Change in the frequency of plasmodial genetic polymorphisms (pfmdr1) as longitudinal markers of antimalarial drug resistance
6. Safety profiles including significant changes in relevant laboratory values

Overall study start date
01/12/2007

Completion date
01/12/2008

Eligibility

Key inclusion criteria
1. Males and females aged between 1 and 5 years inclusive
2. Recurrent Plasmodium falciparum infection after treatment with ACTs in a related main study
3. Parents' or guardians willingness and ability to comply with the study protocol for the duration of the trial

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
5 Years

Sex
Both

Target number of participants

260

Key exclusion criteria
1. Known hypersensitivity to the study drugs
2. Severe malaria
3. Danger signs:
3.1. Not able to drink or breast-feed
3.2. Vomiting (greater than twice in 24 hours)
3.3. Recent history of convulsions (greater than 1 in 24 hours)
3.4. Unconscious state
3.5. Unable to sit or stand
4. Early treatment failure in the main study

Date of first enrolment
01/12/2007

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
Uganda

Study participating centre
Epidemiology and Surveillance Division
Kampala
Uganda
-

Sponsor information

Organisation
Uganda Malaria Surveillance Project (Uganda)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.muucsf.org

Funder(s)

Funder type
Research organisation

Funder Name
Department for International Development (DFID) (UK) - through Malaria Consortium (ref: SUBK026(2))

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	01/11/2013		Yes	No