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An open label, randomised comparative study of supervised and unsupervised amodiaquine plus artesunate treatment for acute uncomplicated Plasmodium falciparum malaria in the Kassena Nankana District of Ghana

Submission date
20/08/2007

Recruitment status
No longer recruiting

Registration date
29/02/2008

Overall study status
Completed

Last Edited
31/05/2019

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

Contact name
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-

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
2004/GD/46

Study information

Scientific Title
An open label, randomised comparative study of supervised and unsupervised amodiaquine plus artesunate treatment for acute uncomplicated Plasmodium falciparum malaria in the Kassena Nankana District of Ghana

Acronym
ASAQ

Study objectives
To compare treatment outcomes (clinical and parasitological) in patients with acute uncomplicated falciparum malaria treated with amodiaquine plus artesunate under a supervised and unsupervised regimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Navrongo Health Research Centre Institutional Review Board. Date of approval: 26 October 2005 (ref: NHRCIRB038)
2. Ghana Health Service Ethical Review Committee. Date of approval: 30 June 2005 (ref: GHS-ERC-05/6/05)

Study design
Open-label randomized design.

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
Acute malaria

Interventions

Supervised group: Each administration of artesuante and amaodiaquine will be supervised by a health professional
Unsupervised group: The participants will receive the first dose as above, but are given the reminder of the drugs for home administration

The doses are:
Artesunate (oral): 4 mg/Kilogram body weight daily for 3 days
Amodiaquine (oral): 10 mg/Kg body weight daily for 3 days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
amodiaquine , artesunate

Primary outcome measure
Adequate clinical and parasite clearance.

Timepoints of measurement: Days 2, 3, 7, 14, 21 and 28

Secondary outcome measures
Parasite and fever clearance times.

Timepoints of measurement: Days 2, 3, 7, 14, 21 and 28

Overall study start date
01/11/2005

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. Signed witnessed informed consent
2. Bodyweight >5 kg
3. P. falciparum mono-infection with parasite density of 2,000-200,000 asexual parasites per microlitre
4. Fever (axillary temperature greater than or equal to 37.5 C) and/or history of fever
5. Haemoglobin >6.0 g/dl

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
350

Total final enrolment
308

Key exclusion criteria
1. Danger signs of severe malaria
2. Severe malnutrition
3. History of allergy to drugs
4. Other underlying chronic diseases

Date of first enrolment
01/11/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
Ghana

Study participating centre
Navrongo Health Research Centre (NHRC)
Navrongo
Ghana
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Sponsor information

Organisation
Ghana Health Service (Ghana)

Sponsor details
Health Research Unit
Accra
Ghana
Box 114

Sponsor type
Government

Website
http://www.ghanahealthservice.org/

ROR
https://ror.org/052ss8w32

Funder(s)

Funder type
Government

Funder Name
The Ghana-Netherlands Health Research Programme (HRP) for Development, Health Research Unit, Ghana Health Service (Ghana)

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	01/10/2008	31/05/2019	Yes	No