# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
20/08/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
29/02/2008	Completed	[X] Results		
<b>Last Edited</b> 31/05/2019	Condition category Infections and Infestations	[] Individual participant data		

# Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Abraham Oduro

#### Contact details

Navrongo Health Research Centre (NHRC) Post office box 114 Navrongo Ghana

## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

Adequate clinical and parasite clearance.

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

#### Key secondary outcome(s))

Parasite and fever clearance times.

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

#### 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

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

All

#### 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)

#### **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**

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