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# A phase IV randomised study to assess the tolerability of artesunate-amodiaquine (AS-AQ) (Winthrop® fixed dose combination [FDC]) and artemether-lumefantrine for the treatment of uncomplicated falciparum malaria in Liberia

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 03/10/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 09/10/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 28/03/2017 | Infections and Infestations | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Richard Smith

**Contact details**
Saclepea CHC
Nimba county
Liberia
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

7071

# Study information

## Scientific Title
A phase IV randomised study to assess the tolerability of artesunate-amodiaquine (AS-AQ) (Winthrop® fixed dose combination [FDC]) and artemether-lumefantrine for the treatment of uncomplicated falciparum malaria in Liberia

## Study objectives
1. To describe clinical tolerability of a fixed dose of AS-AQ (Winthrop® FDC) in adults and children over 6 years with uncomplicated Plasmodium falciparum malaria compared to a non-AQ containing reference therapy, i.e. artemether-lumefantrine
2. To describe serious adverse and drug related adverse events occurring within 1 month of drug administration for both treatments
3. To assess efficacy of treatment at 28 days
4. To describe day 0 and day 7 blood levels of desethyl-amodiaquine and lumefantrine
5. To promote awareness of drug safety issues and pharmacovigilance amongst health-care workers
6. To evaluate the ability of this method to detect serious adverse events and other safety information in the post-registration phase

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. French CPP, approval on 03/07/2008
2. Liberian Ministry of Health and Social Welfare, approval on 23/09/2008

## Study design
Randomised single-blind two-armed single-centre comparative study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

### Interventions
Patients will be equally randomised into the following treatment groups:
1. Artesunate-amodiaquine (AS-AQ Winthrop®, Sanofi-Aventis): tablet strength AS/AQ 100/270 mg. Participants will be dosed according to body weight:
18 - 35.9 kg = 1 x 100/270 mg tablet once daily
Greater than 36 kg = 2 x 100/270 mg tablets once daily
2. Artemether-lumefantrine (Coartem, Novartis): tablet strength A/L 20/120 mg. Participants will be dosed according to body weight:
15 - 24.9 kg = 2 x 20/120 mg tablets twice daily, 8 - 12 hour between dosages
25 - 34.9 kg = 3 x 20/120 mg tablets twice daily, 8 - 12 hour between dosages
Greater than 35 kg = 4 x 20/120 mg tablets twice daily, 8 - 12 hour between dosages

For both arms: 3 days of treatment + 25 follow-up days (study duration/patient = 28 days).

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Artesunate-amodiaquine (AS-AQ) (Winthrop® fixed dose combination [FDC]), artemether-lumefantrine

### Primary outcome measure
To describe clinical tolerability of a fixed dose of AS-AQ (Winthrop® FDC) in adults and children over 6 years with uncomplicated P. falciparum malaria compared to a non-AQ containing reference therapy, i.e. artemether-lumefantrine. The clinical tolerability will be defined as the occurrence of most common adverse events.

### Secondary outcome measures
1. To describe serious adverse and drug related adverse events occurring within 1 month of drug administration for both treatment
2. To assess efficacy of treatment at 28 days (polymerase chain reaction [PCR] genotyping corrected)
3. To describe day 0 and day 7 blood levels of desethyl-amodiaquine and lumefantrine

### Overall study start date
29/09/2008

### Completion date
01/04/2009

## Eligibility

### Key inclusion criteria
1. Aged greater than or equal to 6 years, either sex
2. Weight greater than or equal to 18 kg
3. Symptoms of malaria defined as fever (axillary temperature greater than or equal to 37.5°C), or history of fever in previous 48 hours

4. Microscopic confirmation of asexual stages of P. falciparum or mixed infection
5. Willingness to attend for follow-up
6. Signed informed consent by patient or responsible caregiver

### Participant type(s)
Patient

### Age group
Mixed

### Sex
Both

### Target number of participants
1000 patients

### Key exclusion criteria
1. Pregnancy (pregnancy test to be performed in women of childbearing age)
2. Severe malaria
3. AS-AQ or AL treatment at appropriate dose or more than two doses of another antimalarial in the previous 4 weeks
4. Known hypersensitivity to artemisinin derivates or amodiaquine, or artemether-lumefantrine
5. Severe anaemia (less than 5 g/dl haemoglobin)
6. Concomitant febrile illness if additional medication is required other than antipyretics

### Date of first enrolment
29/09/2008

### Date of final enrolment
01/04/2009

## Locations

### Countries of recruitment
Liberia

### Study participating centre
**Saclepea CHC**
Nimba county
Liberia
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## Sponsor information

### Organisation

Drugs for Neglected Diseases initiative (DNDi) (Switzerland)

### Sponsor details
15 Chemin Louis Dunant
Geneva
Switzerland
CH-1202

### Sponsor type
Research organisation

### Website
http://www.dndi.org/

### ROR
https://ror.org/022mz6y25

## Funder(s)

### Funder type
Research organisation

### Funder Name
Drugs for Neglected Diseases initiative (DNDi) (Switzerland)

## 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 | 17/07/2013 | | Yes | No |
| Results article | results | 17/07/2013 | | Yes | No |