

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

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| Submission date 03/10/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 09/10/2008 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 28/03/2017 | Condition category Infections and Infestations | <input type="checkbox"/> 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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Saclepea CHC
Nimba county
Liberia
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 derivatives 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 |