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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
03/10/2008

Registration date
09/10/2008

Last Edited
28/03/2017

Recruitment status
No longer recruiting

Overall study status
Completed

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
Dr Richard Smith

Contact details
Saclepea CHC
Nimba county
Liberia
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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)

ROR
https://ror.org/022mz6y25

Funder(s)

Funder type
Research organisation

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

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