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Efficacy of amodiaquine-artesunate and artemether-lumefantrine for the treatment of uncomplicated Plasmodium falciparum malaria in Nimba county, Liberia

Submission date
03/10/2008

Recruitment status
No longer recruiting

Registration date
09/10/2008

Overall study status
Completed

Last Edited
28/03/2017

Condition category
Infections and Infestations

[X] 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
7070

Study information

Scientific Title
Efficacy of amodiaquine-artesunate and artemether-lumefantrine for the treatment of uncomplicated Plasmodium falciparum malaria in Nimba county, Liberia

Study objectives
1. To evaluate the efficacy of amodiaquine-artesunate and artemether-lumefantrine among children between 6 and 59 months old suffering from uncomplicated malaria defined as the polymerase chain reaction (PCR)-adjusted cure rates at day 42
2. To assess the safety of amodiaquine-artesunate and artemether-lumefantrine treatment among children between 6 and 59 months old suffering from uncomplicated malaria
3. To assess inter-patient absorption differences possibly influencing efficacy
4. To formulate recommendations for adapted case management in Nimba county

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. French CPP, 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 fixed dose combination (AS/AQ FDC) (artesunate amodiaquine Winthrop® Sanofi Aventis):
1.1. Artesunate 25 mg/amodiaquine 67.5 mg 1 tablet/day for 3 days in children 5 kg to 8.9 kg
1.2. Artesunate 50 mg/amodiaquine 135 mg 1 tablet/day for 3 days in children 9 kg to 17.9 kg
1.3. Artesunate 100 mg/amodiaquine 270 mg 1 tablet/day for 3 days in children 18 kg to 35.9 kg
2. Coartem®: artemether 20 mg - lumefantrine 120 mg co-formulated tabs (Coartem®, Novartis) given as six twice-daily doses over three days:
2.1. One tablet/dose for weight 5 - 14.9 kg (total 6 tablets)
2.2. Two tablets/dose for weight 15 - 24.9 kg (total 12 tablets)
2.3. Three tablets/dose for weight 25 - 34.9 kg (total 18 tablets)
2.4. Four tablets/dose for weight greater than or equal to 35 kg (total 24 tablets)
The second dose will be given 8 to 12 hours after the first dose, given at inclusion. Patients will be given milk, or encouraged to breastfeed, before each dose is taken.

For both arms: 3 days of treatment + 39 follow-up days (study duration/patient = 42 days).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Amodiaquine, artesunate, artemether, lumefantrine

Primary outcome(s)
1. To evaluate the efficacy of both drugs uncorrected by PCR genotyping at day 42 and to compare the re-infection rates
2. To evaluate the PCR corrected and uncorrected efficacy of amodiaquine-artesunate and artemether-lumefantrine on day 28 of follow up

Key secondary outcome(s))
1. To assess the safety of amodiaquine-artesunate and artemether-lumefantrine treatment among children between 6 and 59 months old suffering from uncomplicated malaria by documenting adverse events that occurred during the study, before:
1.1. Day 28
1.2. Day 42
1.3. By documenting serious adverse events (SAE)
2. To assess inter patient absorption differences possibly influencing efficacy by measuring the pharmacokinetic (PK) of amodiaquine and lumefantrine at day 0 and day 7

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. Age group of 6 and 59 months, either sex
2. Weight greater than or equal to 5 kg
3. Slide-confirmed infection with Plasmodium falciparum only (no mixed infections)
4. Asexual parasite density between 2,000 and 200,000/µl of blood, and
5. Measured axillary temperature greater than or equal to 37.5°C or history of fever in the last 48 hours, and
6. High probability of respecting the follow-up visits (residence within 1 hour walking distance from the OPD, no upcoming travel plans, etc.), and
7. Informed consent from a parent or guardian aged at least 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 months

Upper age limit
59 months

Sex
All

Key exclusion criteria
1. General danger signs according to the World Health Organization (WHO) definition
2. Signs of severe/complicated malaria according to the WHO definition
3. Severe anaemia (haemoglobin less than 5 g/dL)
4. Known history of hypersensitivity to any of the study drugs
5. Severe malnutrition (as defined by a weight-for-height below 70% of median and/or symmetrical oedemas involving at least the feet)
6. Concomitant febrile illness judged as due to causes other than malaria with the potential to confound study outcome (measles, acute lower tract respiratory infection, otitis media, tonsillitis, abscesses, severe diarrhoea with dehydration, etc; mild flu shouldn't lead to exclusion)
7. Having received already a full course of the treatment (or one of the treatments) under study in the previous 10 days

Date of first enrolment
17/11/2008

Date of final enrolment
01/07/2009

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
Results article	results	05/09/2016		Yes	No