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To assess the efficacy and tolerability of three antimalarial treatments in The Democratic Republic of Congo (DRC)

Submission date
22/09/2011

Recruitment status
No longer recruiting

Registration date
06/10/2011

Overall study status
Completed

Last Edited
10/02/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Malaria is a serious tropical disease spread by mosquitoes. Antimalarial medication is used to prevent and treat malaria, with the first-line treatment being the first treatment given. We are carrying out a detailed assessment of the effectiveness of the current first-line antimalarial treatment, 5 years after its introduction. We will also assess the effectiveness of two other antimalarial treatments which could replace the first line in the near future, or be proposed as first-line treatment as part of a multiple first-line treatment strategy.

Who can participate?
Children aged 6 to 59 months with uncomplicated malaria

What does the study involve?
Participants are randomly allocated to one of the three treatments. The three treatments are amodiaquine-artesunate, dihydroartemisinin-piperaquine and artemether-lumefantrine. The study is open label, so the doctor and the patients both know which treatment they have been assigned to. All children are hospitalized for four days and given supervised treatment. The effectiveness of the treatment is measured and participants are followed up for 42 days after treatment.

What are the possible benefits and risks of participating?
The results of the study will enable the Ministry of Health to make informed decisions about whether the current national antimalarial treatment guidelines should be updated, and offer possible alternatives.

Where is the study run from?
The study will be conducted in Kinshasa, Democratic Republic of Congo.

When is the study starting and how long is it expected to run for?
September 2011 to December 2012

Who is funding the study?
Oxford University (UK)

Who is the main contact?
Prof Nick PJ Day

Contact information

Type(s)
Scientific

Contact name
Prof Nick PJ Day

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version # 1.01 30 March 2011

Study information

Scientific Title
A randomised study to assess the efficacy and tolerability of three Artemisinin-based combination therapy (ACT) in The Democratic Republic of Congo (DRC)

Study objectives
This study will assess the efficacy of amodiaquine-artesunate for the treatment of uncomplicated P. falciparum malaria in children in Kinshasa, DRC, five years after its introduction as a first line treatment, and compare this with the efficacies of dihydroartemisinin-piperaquine and artemether-lumefantrine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Oxford Tropical Research Ethics Committee (OXTREC), 06/04/2011
2. Ethics Committee of Kinshasa University, Ministry of Higher Education and University, Democratic Republic of Congo (Ministère de l'Enseignement Supérieur et Universitaire, République Démocratique du Congo), 21/04/2011

Study design
Randomised three-arm open 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 below to request a patient information sheet

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

Interventions
This is a randomised, open study, comparing three ACTs, dihydroartemisinin-piperaquine (DHA-PQ), artemetherlumefantrine (ALN) and amodiaquine-artesunate coformulated (AQ-AS), for the treatment of symptomatic uncomplicated falciparum malaria. The study is post-marketing, all three study drugs are in fact commercialized and used worldwide. Our aim is to monitor their efficacy and tolerability in this particular geographical area. Dosage and length of treatment are according to manufacturer. Children aged 6 to 59 months with uncomplicated P. falciparum malaria are randomly assigned to one of the three arms. All children are hospitalized for 3 days and given supervised treatment. Treatment efficacy is measured according to WHO (Methods for surveillance of antimalarial drug, WHO 2009). Patients are followed-up actively weekly for 42 days after treatment. Treatment allocation is concealed until recruitment is confirmed and the laboratory technicians reading all malaria smears have no knowledge of the treatment received by individual patients. Randomisation is in blocks of 15.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Clinical and parasitological cure by day 42 post-treatment
2. Treatment tolerability

Secondary outcome measures
1. The median parasite clearance time (PCT)
3. Fever clearance time (FCT)

Overall study start date
08/09/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Children aged 3 to 59 months
2. Weight ≥ 5 kg [the minimum weight for treatment with artemether-lumefantrine (ALN)]
3. Mono-infection with P. falciparum
4. Parasitaemia of ≥2,000 and ≤200,000 asexual parasites per µL
5. Axillary temperature 37.5 °C or history of fever in the preceding 24 hrs
6. Ability to swallow oral medication
7. Haemoglobin ≥5.0 g/dL
8. Parents/guardians agree to hospitalize the child for the length of treatment (34 days) and bring the patient for planned follow-up visits at day 7, 14, 21, 28, 35, 42
9. Signed consent from guardian / parents

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
684

Key exclusion criteria
1. Danger signs of severe malaria or signs of severe malaria (WHO 2000)
2. Children with severe malnutrition, marasmus or oedematous malnutrition (WHO 2006)
3. Febrile condition due to diseases other than malaria [e.g. measles, acute lower respiratory tract infection, severe diarrhoea with dehydration) or other known underlying chronic or severe diseases (e.g. cardiac, renal or hepatic diseases, human immunodeficiency virus (HIV) / acquired immune deficiency syndrome (AIDS)]
4. History of hypersensitivity reactions or contraindication to any medicine being tested
5. A clear history of adequate antimalarial treatment in the preceding 72 hours with drugs expected to be effective

6. Ongoing prophylaxis with drugs having antimalarial activity such as cotrimoxazole for the prevention of Pneumocisti carini pneumonia in children born to HIV positive women

Date of first enrolment
08/09/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Congo, Democratic Republic

Thailand

Study participating centre
Mahidol University
Bangkok
Thailand
10400

Sponsor information

Organisation
The Centre for Tropical Medicine (UK)

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Sponsor type
University/education

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ROR

https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
Oxford University (UK)

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	01/09/2014		Yes	No