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Intermittent Preventive Treatment for malaria in patient with Sickle Cell Disease

Submission date
08/11/2011

Recruitment status
No longer recruiting

Registration date
14/11/2011

Overall study status
Completed

Last Edited
20/03/2019

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 that kills more than a million people each year, the majority in sub-Saharan Africa. Sickle cell anaemia is an inborn defect of the blood that occurs commonly in parts of the world such as sub-Saharan Africa where malaria is also very common. Sickle cell anaemia is associated with complications such as bone pain and anaemia (shortage of red blood cells). Malaria is an important trigger of these complications. Intermittent preventive treatment (IPT) involves administering antimalarial drugs at predetermined intervals. IPT using the drugs sulfadoxine-pyrimethamine has been found to reduce death and sickness due to malaria in infants, children and pregnant women. Proguanil is among the drugs presently being used for malaria prevention in patient with sickle cell anaemia. The aim of this study is to compare the tolerability and acceptability of supervised bimonthly treatment with either sulfadoxine-pyrimethamine plus amodiaquine (SP+AQ) or mefloquine plus artesunate (MQ+AS), with daily proguanil.

Who can participate?
Children aged 6 months or older with sickle cell anaemia.

What does the study involve?
Participants are randomly allocated into three groups, to receive either bimonthly treatment with SP+AQ, bimonthly treatment with MQ+AS, or daily proguanil. They take this for 12 months. The clinical and laboratory features of malaria are assessed and compared between the three groups.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Ilorin Teaching Hospital (Nigeria).

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

Who is funding the study?
Wellcome Trust (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01319448

Protocol serial number
N/A

Study information

Scientific Title
A randomised trial to compare the safety, tolerability and efficacy of bi-monthly intermittent preventive treatment with either artesunate plus mefloquine or amodiaquine plus sulfadoxine-pyrimethamine with the standard regimen of daily proguanil for the prevention of malaria and related complications in patients with sickle cell anaemia in Nigeria

Acronym
SCD-IPT

Study objectives
Supervised bimonthly courses of treatment with mefloquine-artesunate (MQ+AS), or SP plus amodiaquine (SP+AQ), will be more effective in prevention of malaria and related complications in children with SCA compared to daily doses of proguanil and will be acceptable when taken on a long term basis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene & Tropical Medicine Ethics Committee, 05/05/2011, ref: application No 5942
2. University of Ilorin Teaching Hospital Ethical Review Committee, 06/07/2011

Study design
Open-label randomised trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sickle cell anaemia and malaria prevention

Interventions
Group 1
Daily proguanil: Active Comparator
Standard policy of a supply of proguanil tablets to be taken daily
Intervention: Drug: Proguanil
Assigned intervention Proguanil tablets, 1.5mg/kg/day

Group 2
IPT with MQ+AS bimonthly: Experimental
Intermittent Preventive Treatment (IPT) consisting of a bimonthly course of treatment with mefloquine-artesunate (MQ+AS)
Intervention: Drug: mefloquine plus artesunate
Assigned intervention
Drug: mefloquine plus artesunate
This treatment is given once a day for 3 days. Patients weighing 5-8 kg receive one paediatric tablet per day, those weighing 9-17 kg two paediatric tablets, those weighing 18-29 kg one adult tablet and those weighing 30 kg and two adult tablets

Group 3
IPT with SP+AQ bimonthly: Experimental
IPT with bimonthly course of treatment with sulfadoxine-pyrimethamine plus amodiaquine (SP+AQ)

Assigned Intervention: Drug: Sulfadoxine-pyrimethamine plus amodiaquine supervised at each bimonthly clinic visit (amodiaquine 10mg/kg per day for three days and sulfadoxine-pyrimethamine (25/1.25 mg/kg) on the first day).

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Proguanil, mefloquine, artesunate, sulfadoxine, pyrimethamine, amodiaquine

Primary outcome(s)
1. Incidence of adverse events [Time Frame: 12 months]
2. Adherence to the recommended regimen [Time Frame: 12 months]
3. The co-primary endpoints of the trial will be :
3.1.The occurrence of any solicited adverse event
3.2. The occurrence of vomiting
3.3. The most commonly reported adverse event after IPT treatments and
3.4. Adherence to the regimen ie the number of doses or complete courses of medication received by children in each group as a proportion of the number of doses/complete courses that should have been received

Key secondary outcome(s))
1. Mean haemoglobin concentration 12 months after enrolment
2. Occurrence of other common adverse events such as diarrhoea, skin rash, itching or nausea
3. Number of hospital admissions during the surveillance period
4. Number of blood transfusions received
5. Number of cases of severe malaria during the surveillance period
6. Number of out patient department (OPD) attendances with clinical malaria that meet the case definitions during the surveillance period (malaria episodes over time)
7. Number of patients experiencing bone pain, haemolytic, and aplastic crises

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. Age 6months or older and >=5kg
2. Sickle cell clinic attendant
3. Both males and females
4. Agree to abide by the study protocol
5. Give informed consent and assent
6. Not acutely sick at the time of recruitment
7. Not having additional chronic disease
8. Haemoglobin (Hb) genotype of SS and SC confirmed by electrophoresis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Known allergy to any of the antimalarial drugs use in the trial
2. Severe illnesses requiring urgent admission
3. Treatment with sulfadoxine-pyrimethamine or mefloquine in the previous 2 weeks
4. Patients on cotrimoxazole prophylaxis

Date of first enrolment
05/09/2011

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
Nigeria

Study participating centre
University of Ilorin Teaching Hospital
Ilorin
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00234

Sponsor information

Organisation
Wellcome Trust (UK)

ROR
https://ror.org/029chgv08

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) (WT086153MA)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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	15/08/2015		Yes	No