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Prevention of malaria during pregnancy: intermittent preventive treatment with two versus three doses of sulfadoxine-pyrimethamine

Submission date
27/01/2010

Registration date
13/05/2010

Last Edited
21/07/2011

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Intermittent preventive treatment with two versus three doses of sulfadoxine-pyrimethamine for the prevention of malaria during pregnancy in Mali: an open randomised controlled trial

Study objectives
We hypothesised that intermittent preventive treatment (IPT)-three doses will be as efficacious as IPT-two doses of sulfadoxine-pyrimethamine (SP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Faculty of Medicine, Pharmacy and Odonto-stomatology, University of Bamako approved on the 31st March 2006

Study design
Open randomised controlled trial

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 contact Dr Kassoum Kayentao at kayentao@mrtcbko.org to request a patient information sheet

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

Interventions
Through an open label block randomisation (block size of 20); women were assigned to receive one of the treatment regimens (two or three doses of SP). One treatment dose was 1500 mg of sulfadoxine and 75 mg of pyrimethamine. Sequence of dosing admistration was as follows:
1. Women in the three-doses received the first dose between the 4th - 6th month of gestation, the second dose between 5th - 7th month of gestation, and the third dose no later that the 8th month of gestation
2. Women in the two-dose group received the first dose between the 4th - 6th month of gestation and the second dose no later than the 8th month of gestation. Doses were administered at least one month apart.

All drugs were administered directly by the study team and women were observed for 30 minutes following dosing. Study participants were asked to avoid self medication of anti-malrials other than the study medication and to return to the clinic for scheduled monthly assessment or any unscheduled sick visits. Women received ferrous sulphate (200 mg containing 60 mg of iron) and folic acid (0.4 mg) daily starting two weeks after each SP dosing as recommended by the Ministry of Health.

If malaria was diagnosed during subsequent visits, oral quinine was given 600 mg three times a day over 7 consecutive days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Sulfadoxine-pyrimethamine

Primary outcome measure
Placental malaria. Placental blood was collected from the maternal side of the placenta (after cleaning using filter paper before cutting with cleaned lancet) for thick blood smear for parasitaemia detection.

Secondary outcome measures
1. Low birth weight. Gestational age at delivery was assessed using the Ballard score, and infants were weighed using a digital scale within 24 hours of delivery to measure the incidence of low birth weight.
2. Maternal anaemia. Following delivery, haemoglobin concentration was measured by HemoCue® (Hemocue 201: Anglholm, Sweden) and peripheral parasitaemia was assessed by peripheral blood smear.

Overall study start date
21/04/2006

Completion date
22/02/2010

Eligibility

Key inclusion criteria
1. Aged 14 to 45 years, female pregnant women
2. Gestational age between 16 and 24 weeks
3. Provide consent form
4. Not having chronic disease
5. Willing to terminate the study and follow study conditions

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
406 in each treatment arm (812 in total)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
21/04/2006

Date of final enrolment
22/02/2010

Locations

Countries of recruitment
Mali

Study participating centre
DNS-Mali
Bamako
Mali
BP:23

Sponsor information

Organisation
National Direction of Health (Mali)

Sponsor details
Tomikorobougou
Bamako
Mali
BP:23

Sponsor type
Government

Website
http://dnsmali.net

ROR
https://ror.org/00j73mn11

Funder(s)

Funder type
Government

Funder Name
National Direction of Health (Mali)

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	01/08/2011		Yes	No