

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

Submission date 27/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/07/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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BP:23

Additional identifiers

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

Primary study design

Interventional

Study design

Open randomised controlled trial

Study type(s)

Treatment

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 administration 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 than 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-malarials 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/00j73mn11>

Funder(s)

Funder type

Government

Funder Name

National Direction of Health (Mali)

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	01/08/2011		Yes	No