

Intermittent malaria treatment and iron supplementation for the control of malaria and anaemia in infants in the Forest Belt of rural Ghana: a double-blind randomised controlled trial

Submission date 01/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/10/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
980643

Study information

Scientific Title

Study objectives

To establish whether preventive treatment or iron supplementation given at EPI prevented either severe anaemia or malaria.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received on the 17th June 1999.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions

Double blind placebo controlled trial. One of the following treatments given to children at the time of DPT2, DPT3 and measles vaccination:

1. Iron supplementation and placebo
2. Placebo and sulphadoxine pyrimethamine
3. Iron supplementation and sulphadoxine pyrimethamine

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Iron supplementation, sulphadoxine pyrimethamine

Primary outcome(s)

1. To assess the effectiveness of intermittent malaria treatment (1.25 mg pyrimethamine plus 25 mg sulfadoxine/kg) given at 10 weeks, 14 weeks and 9 months through the EPI programme in the control of malaria and severe anaemia in infancy
2. To determine the effect of intermittent malaria treatment in infancy on the risk of malaria and anaemia in childhood after completion of trial
3. To evaluate the effect of daily iron supplementation (2 mg/kg) given from 10 weeks to 12

months through the EPI programme on the control of malaria and severe anaemia
4. To assess the socio-cultural factors influencing acceptability of treatment modalities
5. To evaluate the cost effectiveness of interventions

Key secondary outcome(s)

No secondary outcome measures

Completion date

17/06/2001

Eligibility

Key inclusion criteria

All infants aged at least 10 weeks attending a Mother and Child Health (MCH) Clinic or Child Welfare Clinic (CWC) in the Afigya-Sekyere District, Ashanti Region and are permanent residents in the district. Their mothers or main carers should have given informed consent to participate in the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Infants who are not permanent residents of Afigya-Sekyere District, Ashanti Region.

Date of first enrolment

17/06/1999

Date of final enrolment

17/06/2001

Locations

Countries of recruitment

Ghana

Switzerland

Study participating centre

20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

Funder Name

United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)
/World Bank/World Health Organization (WHO) - Special Programme for Research and Training
in Tropical Diseases (TDR)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration