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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

Registration date
01/02/2006

Last Edited
02/10/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

Study design
Randomised controlled trial

Primary study design
Interventional

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