

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

☐ Prospectively registered

☐ Protocol

Registration date

01/02/2006

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

02/10/2007

Condition category

Infections and Infestations

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

17/06/1999

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

450 infants/arm - 1800 infants in total randomised

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)

Sponsor details

20, Avenue Appia

Geneva-27

Switzerland

CH 1211

Sponsor type

Research organisation

Website

<http://www.who.int/>

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**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