

The prevention of malaria and anaemia in infants through iron supplementation and intermittent malaria treatment administered through the Expanded Programme on Immunization (EPI) Scheme (Tanzania)

Submission date 01/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/02/2006	Overall study status Completed	☐ Protocol
Last Edited 21/04/2010	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ 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

Protocol serial number
980483

Study information

Scientific Title

Study objectives

To evaluate the impact of iron supplementation and the effectiveness of malaria intermittent treatment on the prevention of malaria and severe anaemia in infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received on the 26th June 1998.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions

All children receive oral daily iron syrup at a dosage of 2 mg/kg/day and will be randomly allocated to receive either intermittent malaria treatment (sulfadoxine-pyrimethamine) or a placebo at DPT2, DPT3 and measles vaccinations.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sulfadoxine-pyrimethamine

Primary outcome(s)

Incidence of clinical malaria and severe anaemia episodes in each group by 12 months of age.

Key secondary outcome(s)

1. Incidence of clinical malaria and severe anaemia episodes up to 18 months of age
2. Incidence of clinical malaria and severe anaemia from 10 to 18 months of age
3. Prevalence of malaria parasitaemia at 12 and 18 months of age
4. Prevalence of severe and moderate anaemia at 12 and 18 months of age
5. Total number of admissions and outpatient attendances

Completion date

26/06/2000

Eligibility

Key inclusion criteria

All children who attend the Mother and Child Health (MCH) clinic for their second Diphtheria, Pertussis, Tetanus (DPT) and polio immunisations and who are permanent residents in the study area of Ifakara town.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

Female

Key exclusion criteria

Infants who are not permanent residents in Ifakara.

Date of first enrolment

26/06/1998

Date of final enrolment

26/06/2000

Locations

Countries of recruitment

Switzerland

Tanzania

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results at	12/05/2001		Yes	No
Results article	follow-up results	01/04/2005		Yes	No