

# 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)

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| <b>Submission date</b><br>01/02/2006   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>01/02/2006 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>21/04/2010       | <b>Condition category</b><br>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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

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.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

26/06/1998

### **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

### **Age group**

Child

### **Sex**

Female

### **Target number of participants**

340 infants in each group to be randomised, 680 total

### **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)

**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

## Study outputs

| Output type                     | Details           | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|-------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results at        | 12/05/2001   |            | Yes            | No              |
| <a href="#">Results article</a> | follow-up results | 01/04/2005   |            | Yes            | No              |