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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

Registration date
01/02/2006

Last Edited
21/04/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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?
Results article	results at	12/05/2001		Yes	No
Results article	follow-up results	01/04/2005		Yes	No