

Randomised placebo controlled trial of intermittent malaria treatment through the Expanded Programme on Immunisation (EPI) to prevent malaria/anaemia in infants (Kenya)

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| Submission date 01/02/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 01/02/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 19/07/2021 | Condition category 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Randomised placebo controlled trial of intermittent malaria treatment through the Expanded Programme on Immunisation (EPI) to prevent malaria/anaemia in infants (Kenya)

Study objectives

To establish whether preventive treatment given at EPI prevented either severe anaemia or malaria.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received on the 15th December 1999.

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

Sulphadoxine-pyrimethamine or placebo given at EPI visits DPT2, DPT3 and measles. Collection of sera to establish impact (if any) upon EPI antigens.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sulphadoxine-Pyrimethamine (SP)

Primary outcome measure

1. Effectiveness of intermittent malaria treatment of infants with SP (versus placebo) within the Kenya EPI schedule in preventing severe anaemia and malaria
2. Assessment of serological responses to EPI vaccines in children receiving SP versus those receiving placebo for SP

Secondary outcome measures

1. Determine whether intermittent malaria treatment results in a rebound effect of more episodes of malaria after treatment is stopped
2. Determine whether intermittent malaria treatment results in improved growth of infants

Overall study start date

15/12/1999

Completion date

15/12/2001

Eligibility**Key inclusion criteria**

1. Infants of both gender whose parents or guardians give consent and agree to participate in the study for at least eighteen months
2. Infants who will be presenting to the clinic for their second Diphtheria, Pertussis, Tetanus (DPT) and second Oral Polio Vaccine (OPV) immunisations and are aged less than one

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

900 infants randomised

Key exclusion criteria

1. Infants with known hypersensitivity to study drugs
2. Infants with congenital malformations and history of haemolytic anaemia
3. Infants with a history of blood transfusion in the previous week
4. SP treatment in the previous two weeks

Date of first enrolment

15/12/1999

Date of final enrolment

15/12/2001

Locations

Countries of recruitment

Kenya

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

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 | | 15/09/2012 | 19/07/2021 | Yes | No |