

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

Submission date 01/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/02/2006	Overall study status Completed	☐ Protocol
Last Edited 19/07/2021	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

Contact name

Dr Melba Gomes

Contact details

20, Avenue Appia

Geneva-27

Switzerland

CH 1211

+41 (0)22 791 3813

gomesm@who.int

Additional identifiers

Protocol serial number

990354

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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