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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

Registration date
01/02/2006

Overall study status
Completed

Last Edited
19/07/2021

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

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

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

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