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Intermittent Preventive Therapy Post-Discharge: an innovative approach in the prevention of rebound severe malaria anaemia and mortality in young children

Submission date
18/05/2006

Recruitment status
No longer recruiting

Registration date
19/06/2006

Overall study status
Completed

Last Edited
10/04/2012

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
N/A

Study information

Scientific Title
Intermittent Preventive Therapy Post-Discharge: an innovative approach in the prevention of rebound severe malaria anaemia and mortality in young children - a randomised double-blind placebo controlled multicentre study

Acronym
IPTpd

Study objectives
To compare the efficacy of a single treatment course with lumefantrine-artemether (Coartem®) at discharge to three treatment courses with Coartem® given at discharge, 1 and 2 months (intermittent preventive therapy post-discharge [IPTpd]), to standard antimalarial therapy of oral sulfadoxine-pyrimethamine (SP) in Malawi, in the post-discharge management of children, aged 4-59 months, who have recovered from severe malarial anaemia by assessing mean haemoglobin concentration, and the incidence of rebound severe anaemia, clinical malaria and death by 3 and 6 months.

As of 22/04/2010 this record was updated; all changes can be found in the relevant fields with the above update date. At this time, the anticipated end date of this trial was also updated; the initial anticipated end date at the time of registration was 01/12/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by College of Medicine Research and Ethics Committee on 25/02/05, reference number: P.03/04/287 and by Liverpool Research and Ethics Committee on 09/02/05, reference number: 05.01

Study design
Randomised, double-blind, placebo-controlled, multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Severe malarial anaemia

Interventions
Patients are randomised into one of the following groups:
Group A - lumefantrine-artemether, single 3-day course at enrolment
Group B - lumefantrine-artemether, three 3-day courses (at enrolment, at 1 month, and at 2 months)
Group C - sulfadoxine-pyrimethamine (SP), single dose at enrolment (added 22/04/2010: group C dropped out following amendments to protocol)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
lumefantrine-artemether (Coartem®), sulfadoxine-pyrimethamine

Primary outcome measure
Current information as of 22/04/2010:
The incidence of rebound severe anaemia (Hb less than 5 g/L), severe malaria (hospital admissions requiring quinine) or death (a composite endpoint) between 1 and 6 months after enrolment.

Initial information at time of registration:
Mean haemoglobin at three months

Secondary outcome measures
Current information as of 22/04/2010:
1. The incidence of sick-child's clinic visits due to clinical malaria by 3 and 6 months
2. The incidence of all-cause sick-child's clinic visits by 3 and 6 months
3. The incidence of all cause re-hospitalisation between 1 - 3 and 1 - 6 months after enrolment
4. The incidence of the three individual components of the composite endpoint (severe anaemia, severe malaria, death) between 1 - 3 and 1 - 6 months after enrolment
5. Mean haemoglobin at 6 months
6. Incidence of adverse events by 3 and 6 months
7. Mean corrected heart rate (QTc) prolongation by 3 days

Initial information at time of registration:
1. The incidence of sick-child's clinic visits due to clinical malaria by 3 and 6 months
2. The incidence of rebound severe anaemia (Hb <5 g/l)
3. The incidence of death by 3 and 6 months
4. Mean haemoglobin at 6 months
5. Incidence of adverse events by 3 and 6 months
6. Mean corrected heart rate (QTc) prolongation by 3 days

Overall study start date
22/05/2006

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Haemoglobin <5.0 g/dl or packed cell volume (PCV) <15% on admission to the hospital
2. Plasmodium falciparum malaria (any documented parasitaemia) at the time of admission to the hospital or within 24 hours prior to admission
3. Aged between 4 months (inclusive) and 59 months (inclusive) at the time of randomization
4. Bodyweight >5 kg at the time of randomization
5. Subject completed blood transfusion(s) in accordance with routine hospital practice
6. Subject completed intravenous (IV) quinine in accordance with routine hospital practice
7. Able to feed (for breastfed children) or eat (for older children)
8. Able to sit unaided
9. Provision of informed consent by parent or guardian

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
1280 (initial). As of 22/04/2010: 1650 participants or 126 events

Key exclusion criteria
1. Recognised, specific other cause of severe anaemia at the time of admission to the hospital (e.g. trauma, haematological malignancy, known bleeding disorder, known sickle cell disease)
2. Previous enrolment in the present study
3. Severe anaemia (haemoglobin <5.0 g/dl) at the time of randomization
4. Known hypersensitivity to any of the study drugs
5. Documented intake of Coartem® (≥4 doses) or SP within 1 week prior to admission
6. Child resides outside of catchment area during the course of the study (6 months)
7. Known need at the time of randomization for concomitant prohibited medication during the 2 months randomized treatment period
8. Ongoing participation into another clinical trial involving ongoing or scheduled treatment with medicinal products during the course of the study (6 months)

9. Known need, or scheduled surgery during the course of the study (6 months)
10. Suspected non-compliance with the follow-up schedule

Date of first enrolment
22/05/2006

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
England

Malawi

United Kingdom

Study participating centre
Liverpool School of Tropical Medicine
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Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

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Sponsor type
University/education

Website
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ROR

https://ror.org/03svjbs84

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases (NACCAP) (Netherlands) (ref: W 07.05.202.00)

Funder Name
UBS Optimus Foundation (Switzerland)

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	01/03/2012		Yes	No