ISRCTN27290841 https://doi.org/10.1186/ISRCTN27290841

Safety and efficacy of the combination of chloroquine and methylene blue in the treatment of uncomplicated falciparum malaria in young children of Burkina Faso

Submission date
12/12/2003

Recruitment status
No longer recruiting

Registration date
06/02/2004

Overall study status
Completed

Last Edited
19/02/2008

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

Acronym
BlueCQ2

Study objectives
Safe, effective and affordable drug combinations against falciparum malaria are urgently needed for the poor populations in malaria endemic countries. Methylene blue (MB) combined with chloroquine (CQ) has been considered as one promising new regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The protocol was approved by the Ethics Committee of the Medical Faculty of Heidelberg University and the local Ethics Committee in Burkina Faso.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Uncomplicated falciparum malaria

Interventions
Arm A (N = 45): 25 mg/kg oral chloroquine within 3 days
Arm B (N = 180): 25 mg/kg oral chloroquine and 15 mg/kg methylene blue within 3 days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Chloroquine, methylene

Primary outcome measure
Incidence of severe haemolysis or other serious adverse events (SAEs).

Secondary outcome measures
Efficacy outcomes were defined according to the WHO 2003 classification system.

Overall study start date
01/01/2004

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Children (6 - 59 months) with uncomplicated falciparum malaria
2. Greater than or equal to 2000 Plasmodium falciparum
3. Burkinabe nationality

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Not Specified

Target number of participants
225

Key exclusion criteria
1. Complicated or severe malaria (repeated vomiting, seizures or other neurological impairment)
2. Anaemia (haemoglobin less than 8 g/dl or haematocrit less than 24%)
3. Any other apparent significant disease (e.g. pneumonia, meningitis, hepatitis, severe diarrhoea, measles, severe malnutrition)

Date of first enrolment

01/01/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Burkina Faso

Germany

Study participating centre
Department of Tropical Hygiene and Public Health
Heidelberg
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Sponsor information

Organisation
DSM Fine Chemicals (Austria)

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Sponsor type
Industry

ROR
https://ror.org/01j7tpx52

Funder(s)

Funder type
Industry

Funder Name
DSM Fine Chemicals (Austria) - Dream Award

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	22/09/2005		Yes	No