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Dose finding for a safe and efficacious combination of chloroquine (CQ) and methylene blue in the treatment of uncomplicated falciparum malaria in young children of Burkina Faso

Submission date
24/05/2005

Registration date
26/10/2005

Last Edited
31/08/2011

Recruitment status
No longer recruiting

Overall study status
Completed

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

Protocol serial number
BlueCQ3

Study information

Scientific Title

Acronym
BlueCQ3

Study objectives
H_0 (safety): Probability of a relevant adverse event greater or equal to 10%
H_0 (efficacy): Probability of a treatment failure (TF) greater or equal to 15%
(used as criteria to proceed with the next higher dosage level)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Arm A (N = 288): Standard CQ + Methylene blue twice daily (3 consecutive dose levels)
Arm B (N = 288): Standard CQ + Methylene blue four times daily (3 consecutive dose levels)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Chloroquine (CQ) and methylene blue

Primary outcome(s)
1. Incidence of relevant adverse events
2. Incidence of treatment failures (TF)

Key secondary outcome(s))

1. Incidence of early treatment failure (ETF)
2. Incidence of late clinical failures (LCF)
3. Incidence of late parasitological failures (LPF)
4. Fever clearance time
5. Parasite clearance time
6. Change in haemoglobin after 4 (or 7) and 14 days compared to baseline
7. Incidence of observed and self-reported non-serious adverse events over the 14 days observation period
8. Whole blood CQ and Methylene blue kinetics (mean area under the concentrationtime curve [AUC], C[max], T[max], elimination half life)
9. Monitoring of concomitant drug intake
10. G6PD assessment based on PCR

Completion date
31/10/2004

Eligibility

Key inclusion criteria
Children (6-59 months), with uncomplicated falciparum malaria, ≥2000 Plasmodium falciparum, Burkinabe nationality

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
59 months

Sex
All

Key exclusion criteria
1. Complicated or severe malaria
2. Hospitalised before for the same trial
3. Any apparent significant disease other than malaria
4. Hyperparasitaemia (>100,000/µl)
5. Patient is included in another trial

Date of first enrolment
01/07/2004

Date of final enrolment
31/10/2004

Locations

Countries of recruitment
Burkina Faso

Germany

Study participating centre
Department of Tropical Hygiene and Public Health
Heidelberg
Germany
D-69120

Sponsor information

Organisation
DSM Fine Chemicals (Austria)

ROR
https://ror.org/01j7tpx52

Funder(s)

Funder type
Industry

Funder Name
DSM Fine Chemicals, Dream Award (Netherlands)

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	results	08/10/2006		Yes	No