

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

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

26/10/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

31/08/2011

Condition category

Infections and Infestations

☐ 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

H₀ (safety): Probability of a relevant adverse event greater or equal to 10%

H₀ (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

Primary study design

Interventional

Study design

Randomised controlled trial

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 ($>100,000/\mu\text{l}$)
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

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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