

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	<input type="checkbox"/> Prospectively registered
Registration date 06/02/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/02/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Olaf Müller

Contact details

Department of Tropical Hygiene and Public Health
University of Heidelberg
Heidelberg
Germany
D-69120
+49 (0)6221 56 5035
Olaf.Mueller@urz.uni-heidelberg.de

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

Germany

D-69120

Sponsor information

Organisation

DSM Fine Chemicals (Austria)

Sponsor details

c/o Dr. Wolfgang Schiek

St. Peter-Str. 25

PO Box 933

Linz

Austria

A-4021

+43 (0)732 6916 2150

wolfgang.schiek@dsm.com

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