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Malaria study - bulaquine versus primaquine

Submission date	Recruitment status	[_] Prospectively registered
23/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/09/2017	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Malaria study - bulaquine versus primaquine

Acronym
BQ vs PQ

Study objectives
To assess whether bulaquine has superior gametocytocidal activity versus primaquine for Plasmodium falciparum malaria

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes, protocol approved by the Ethics Committee of the Seth GS Medical College and KEM Hospital, Mumbai, India

Study design
Randomised, parallel group

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 P. falciparum malaria

Interventions
Patients are randomised to receive either one of two gametocytocidal drugs: bulaquine 75 mg or primaquine 45 mg

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Bulaquine, primaquine

Primary outcome measure
Gametocytemia at days 8, 15, 22 and 29 of follow-up

Secondary outcome measures
Gametocyte viability at days 8, 15, 22 and 29

Overall study start date
01/06/2003

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Aged more than 16 years
2. Uncomplicated Plasmodium falciparum malaria
3. Gametocyte count more than 55 /ul within 72 hours of diagnosis, irrespective of asexual parasitemia
4. Willing to give written, informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
93

Key exclusion criteria
1. Pregnancy
2. Lactation
3. Allergy to primaquine or bulaquine
4. Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
5. Co-infection with Plasmodium vivax

Date of first enrolment
01/06/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
India

Study participating centre
Not provided at time of registration
Dean, Professor and Head
Mumbai
India
400012

Sponsor information

Organisation
Indian Council of Medical Research

Sponsor details
Ansari Nagar
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Sponsor type
Government

Website
http://www.icmr.nic.in

ROR
https://ror.org/0492wrx28

Funder(s)

Funder type
Government

Funder Name
The project was undertaken as part of the Indian Council of Medical Research centre for Advanced Research in Clinical Pharmacology at the department of clinical pharmacology, Seth GS Medical College & KEM Hospital, Mumbai, India

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	01/02/2006		Yes	No
Other publications		01/12/2006		Yes	No