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A randomised, open label, controlled trial to assess the efficacy and safety of dihydroartemisinin-piperaquine for the treatment of primary and the prevention of secondary infections with Plasmodium falciparum

Submission date	Recruitment status	[_] Prospectively registered
09/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2012	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Steffen Borrmann

Contact details
Im Neuenheimer Feld 350
Heidelberg
Germany
69120
+49 (0)6221 56 7756
steffen.borrmann@urz.uni-heidelberg.de

Additional identifiers

Protocol serial number
1.0.6

Study information

Scientific Title
A randomised open label study to assess the safety and efficacy of dihydroartemisinin-piperaquine (Artekin™) compared with lumefantrine-artemether (Coartem®) for the treatment of uncomplicated Plasmodium falciparum malaria in Kenyan children

Study objectives
Dihydroartemisinin-piperaquine is at least as efficacious as artemether-lumefantrine for the treatment of primary and the prevention of secondary infections with Plasmodium falciparum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Kenya Medical Research Institute, National Ethic Review Committee (Kenya) on the 26th June 2005
2. University of Oxford, Oxford Tropical Research Ethics Committee (UK) on the 6th July 2005
3. University of Heidelberg School of Medicine, Ethics Committee (Germany) on the 8th August 2005

Primary study design
Interventional

Study design
Randomised, open label, controlled trial

Study type(s)
Treatment

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

Interventions
1. Three-day, three-dose regimen of dihydroartemisinin-piperaquine (Artekin™); co-formulation: target dose of 2 mg/kg/ once per day of dihydroartemisinin and target dose of 18 mg/kg/once per day of piperaquine
2. Three-day, six-dose regimen of artemether-lumefantrine (Coartem®); co-formulation containing 20 mg of artemether and 120 mg of lumefantrine:
2.1. 5 kg to less than 15 kg: one tablet/twice per day
2.2. 15 kg to less than 25 kg: two tablets/twice per day
2.3. 25 kg to less than 35 kg: three tablets/twice per day

Patients are followed-up for 84 days.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Dihydroartemisinin-piperaquine (Artekin™), lumefantrine-artemether (Coartem®)

Primary outcome(s)
1. The cure ratio of dihydroartemisinin-piperaquine is non-inferior to that of artemether-lumefantrine (non-inferiority margin = 5%)
2. The cure ratio of dihydroartemisinin-piperaquine is at least 90%

Key secondary outcome(s)
1. Polymerase chain reaction (PCR)-uncorrected day 28 cure ratio
2. Safety profiles of the two treatments
3. Time to asexual parasite clearance (PCT)
4. Time to fever clearance (FCT)
5. Gametocyte prevalence and density on days 7, 14, 28, 42, 63 and 84
6. Haematological recovery (Haemoglobin [Hb] changes) from day 0 to day 28, day 42, and day 84
7. Cure ratios at day 42 (PCR corrected and PCR uncorrected)
8. Cure ratios at day 63 (PCR corrected and PCR uncorrected)
9. Cure ratios at day 84 (PCR corrected and PCR uncorrected)
10. Rate of PCR-confirmed reinfections to estimate the chemoprophylactic effect of dihydroartemisinin-piperaquine

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Males and females aged between 6 months and 59 months inclusive
2. Body weight of 5 kg and above
3. Microscopically confirmed, monoinfection of Plasmodium falciparum (parasitaemia greater than or equal to 2,000/µL to 200,000/µL)
4. History of fever in the previous 24 hours or presence of fever (axillary temperature at greater than or equal to 37.5°C)
5. Signed informed consent by the parents or guardians
6. Parents or guardians willingness and ability to comply with the study protocol for the duration of the trial

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. Participation in any investigational drug study during the previous 30 days
2. Known hypersensitivity to the study drugs
3. Severe malaria
4. Danger signs: not able to drink or breast-feed, vomiting (greater than twice in 24 hours), recent history of convulsions (greater than one in 24 hours), unconscious state, unable to sit or stand
5. Electrocardiogram (ECG) abnormality that requires urgent management
6. Presence of intercurrent illness or any condition which in the judgment of the investigator would place the subject at undue risk or interfere with the results of the study
7. Severe malnutrition (defined as weight for height less than 70% of the median National Center for Health Statistics [NCHS]/World Health Organisation [WHO] reference)

Date of first enrolment
01/09/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Germany

Kenya

Study participating centre
Im Neuenheimer Feld 350
Heidelberg
Germany
69120

Sponsor information

Organisation
University of Heidelberg School of Medicine (Germany)

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Research organisation

Funder Name
Medicines for Malaria Venture (MMV) (Switzerland)

Alternative Name(s)
MMV

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Switzerland

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

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	01/10/2011		Yes	No