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A randomised community based study to assess the safety, efficacy of dihydroartemisinin-piperaquine (artekin) for the treatment of uncomplicated falciparum malaria

Submission date
14/10/2005

Recruitment status
No longer recruiting

Registration date
14/10/2005

Overall study status
Completed

Last Edited
19/06/2015

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
061330

Study information

Scientific Title
A randomised community based study to assess the safety, efficacy of dihydroartemisinin-piperaquine (artekin) for the treatment of uncomplicated falciparum malaria

Acronym
AU Study

Study objectives
Artekin is an exciting, new and relatively low cost antimalarial drug. It is a fixed coformulation containing dihydroartemisinin and piperaquine. The two drugs have been used extensively before as single agents. The objectives of the trial are:
1. To determine the optimum regimen of artemisinin derivative for maximum efficacy of the dihydroartemisinin-piperaquine combination
2. To compare the efficacy of dihydroartemisinin-piperaquine to that of the antimalarial treatment in current use i.e. mefloquine-artesunate three-day regimen (MAS3)
3. To assess the drug in terms of safety and tolerability in adults and children

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Open-label randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malaria

Interventions
Open label randomised controlled trial comparing the efficacy of dihydroartemisinin-piperaquine to that of the antimalarial treatment in current use i.e. mefloquine-artesunate three-day regimen (MAS3).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dihydroartemisinin-piperaquine, mefloquine-artesunate

Primary outcome(s)

The 56 day (community) cure rates are the markers of therapeutic efficacy for this trial.

Key secondary outcome(s))
Secondary endpoints are frequency of adverse events in the two Artekin groups.

Completion date
01/11/2004

Eligibility

Key inclusion criteria
1. Adults or children
2. Symptomatic of malaria infection, i.e. history of fever or presence of fever more than 37.5 °C
3. Microscopic confirmation of asexual stages of P. falciparum or mixed infection (5/500 white blood cells)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Pregnancy or lactation
2. P.falciparum asexual stage parasitaemia greater than or equal to 4% red blood cells (175,000 /µl)
3. Signs or symptoms of severe malaria

Date of first enrolment
01/08/2002

Date of final enrolment
01/08/2004

Locations

Countries of recruitment
Viet Nam

Study participating centre
Hospital for Tropical Diseases
Ho Chi Minh City

Viet Nam
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Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) (grant ref: 061330)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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	03/01/2004		Yes	No