

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	<input type="checkbox"/> Prospectively registered
Registration date 14/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/06/2015	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Secondary endpoints are frequency of adverse events in the two Artekin groups.

Overall study start date

01/08/2002

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

Age group

Mixed

Sex

Both

Target number of participants

To be added

Key exclusion criteria

1. Pregnancy or lactation
2. P.falciparum asexual stage parasitaemia greater than or equal to 4% red blood cells (175,000 / μ l)
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

5

Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

University Offices

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OX1 2JD

+44 (0)1865 270143

research.services@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

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

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	03/01/2004		Yes	No