A randomised, open comparative study of Dihydroartemisinin-piperaquine versus Chloroquine for the treatment of Vivax malaria

Submission date Recruitment status [X] Prospectively registered 06/08/2006 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 08/08/2006 Completed [X] Results [] Individual participant data Last Edited Condition category Infections and Infestations 20/03/2013

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Francois Nosten

Contact details

Shoklo Malaria Research Unit 68/30 Baan Tung Road Mae Sot Thailand 63110 +66 (0)55 545 021 SMRU@tropmedres.ac

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 041843; 027/05

Study information

Scientific Title

Acronym

DCV

Study objectives

The combination of dihydroartemisinin and piperaquine is as effective as chloroquine in the treatment of Plasmodium vivax infections.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford Tropical Ethics Research Committee approval gained (reference number: 027-05).

Study design

Double blind randomised, open comparative trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Uncomplicated vivax malaria

Interventions

Dihydroartemisinin-piperaquine versus Chloroquine treatment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dihydroartemisinin, piperaquine, chloroquine

Primary outcome measure

Day 63 cure

Secondary outcome measures

Safety

Overall study start date

15/08/2006

Completion date

31/12/2007

Eligibility

Key inclusion criteria

- 1. Males and Females aged over 12 months
- 2. Body weight more 5 kg
- 3. Microscopically confirmed, mono-infection of Plasmodium vivax (parasitaemia more than or equal to 5/500 White Blood Cells [WBC])
- 4. Fever (axillary temperature more than or equal to 37.5°C) OR history of fever
- 5. Informed consent obtained by patients and in the case of children, by parents or quardians
- 6. Willingness and ability to comply with the study protocol

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

500

Key exclusion criteria

- 1. Known hypersensitivity to the study drugs
- 2. Presence of intercurrent illness or any condition which in the judgement of the investigator would place the subject at undue risk or interfere with the results of the study
- 3. Pregnancy or lactation, urine test for beta human Chorionic Gonadotropin (beta-hCG) to be performed on any woman of child bearing age
- 4. Mefloquine treatment in the previous 60 days
- 5. Dapsone Pyrimethamine (DP) treatment in the previous three months

Date of first enrolment

15/08/2006

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Thailand

Study participating centre Shoklo Malaria Research Unit

Mae Sot Thailand 63110

Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

Centre for Clinical Vaccinology and Tropical Medicine Churchill Hospital Old Road Headington Oxford England United Kingdom OX3 7LJ +44 (0)1865 857433 paul.hogben@ndm.ox.ac.uk

Sponsor type

University/education

Website

http://www.tropicalmedicine.ox.ac.uk/Index.htm

ROR

https://ror.org/052gg0110

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 041843)

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	01/11/2011		Yes	No