ISRCTN87827353 https://doi.org/10.1186/ISRCTN87827353

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

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

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 guardians
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