A randomised, double-blind, efficacy and dose finding study of intermittent preventive treatment with dihydroartemisinin-piperaquine for prevention of malaria

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

Study information

Scientific Title

Acronym

DCIPT

Study objectives

The combination of dihydroartemisinin and piperaquine is effective in the prevention of Plasmodium falciparum malaria.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford Tropical Ethics Research Committee approval gained (reference number: 028-05).

Study design

Double blind, placebo controlled 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

Plasmodium falciparum malaria

Interventions

Intermittent Preventive Treatment (IPT) of dihydroartemisinin and piperaquine versus a placebo.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dihydroartemisinin and piperaquine

Primary outcome measure

Incidence of malaria

Secondary outcome measures

Safety

Overall study start date

15/08/2006

Completion date

31/12/2007

Eligibility

Key inclusion criteria

- 1. Male
- 2. Aged over 18 years
- 3. Willingness to attend for follow up for nine months
- 4. Written informed consent given to participate in the trial

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

780

Key exclusion criteria

- 1. Malaria asexual stage parasitaemia
- 2. Dapsone Pyrimethamine (DP) treatment within the past six months
- 3. Mefloquine treatment within the past two months
- 4. Known hypersensitivity to artemisinins or DP

Date of first enrolment

15/08/2006

Date of final enrolment

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 Oxford England United Kingdom OX3 7LJ +44 (0)1865 857433 paul.hogben@ndm.ox.ac.uk

Sponsor type

University/education

Website

http://www.ccvtm.ox.ac.uk/

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	01/03/2012		Yes	No