

Co-Artemeter in pregnancy - a pilot study (Thailand)

Submission date 07/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/01/2009	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

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RPC043

Study information

Scientific Title

Study hypothesis

That three day Co-Artemeter (artemether-lumefantrine) has a 4% failure rate compared with an estimated 16% failure rate for seven day artesunate (standard treatment).

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethical Committee of the Faculty of Tropical Medicine, Mahidol University in Bangkok
2. OXTREC (Oxford Tropical Research Ethic Committee)
3. World Health Organization (WHO) Ethics Review Committee

Study design

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

Condition

Malaria in pregnancy

Interventions

Group 1: Artesunate 50 mg tablets (2 mg/kg/day) for seven days

Group 2: Co-artemether (20/120 mg artemether/lumefantrine) four tablets twice a day for three days with 200 ml of chocolate milk at each dose

Please note that the completion of the 12-month follow up of infants born to women enrolled in the study was on 21st January 2008. The previous anticipated end date of this trial was 31/12 /2008.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Co-Artemeter (artemether-lumefantrine), artesunate.

Primary outcome measure

Polymerase Chain Reaction (PCR) adjusted parasitological cure, at day 42 or at delivery depending on which occurs last.

Secondary outcome measures

Other outcomes include:

1. Gametocyte carriage
2. Pharmacokinetic parameters including the plasma lumefantrine levels at day seven as a marker of absorption as well as the infant development during the first year of life
3. The histo-pathology examination (presence of parasites, pigments, monocytes infiltrations and other placental changes) of the placenta

Overall study start date

06/02/2004

Overall study end date

21/01/2008

Eligibility

Participant inclusion criteria

1. Pregnant women with uncomplicated falciparum or mixed infection (i.e. Plasmodium falciparum and Plasmodium vivax), symptomatic or not, in the second or third trimester, who have failed after a course of quinine for seven days
2. Willing and able to participate and comply with the study protocol
3. Attend the Shoklo Malaria Research Unit (SMRU) AnteNatal Clinics (ANCs) regularly
4. Agree to deliver at SMRU

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

250

Participant exclusion criteria

1. Splenectomy
2. A known chronic disease (cardiac, renal, hepatic)
3. Known haemoglobinopathy
4. Known hepatic or renal impairment

5. Inability to follow the ANC consultation
6. History of alcohol or narcotic abuse
7. Inability to tolerate oral treatment
8. Severe and complicated malaria
9. Known hypersensitivity to artemisinin derivatives
10. Patient taking any drug inhibiting the cytochrome enzyme CYP3A4 or drug which is metabolised by cytochrome enzyme CYP2D6 or family
11. History of sudden death or of prolongation of QTc interval on electrocardiogram (ECG)
12. Patients with cardiac arrhythmia, Congestive Cardiac Failure (CCF), or bradycardia accompanied by reduced left ventricular function
13. Intake of drugs that prolong QTc interval

Recruitment start date

06/02/2004

Recruitment end date

21/01/2008

Locations

Countries of recruitment

Switzerland

Thailand

Study participating centre**World Health Organization**

Geneva -27

Switzerland

CH 1211

Sponsor information

Organisation

UNICEF/UNDP/World Bank/WHO - Special Programme for Research and Training in Tropical Diseases (TDR)

Sponsor details

World Health Organization

20 Avenue Appia

Geneva-27

Switzerland

CH 1211

Sponsor type

Research organisation

Website

http://www.who.int

ROR

https://ror.org/01f80g185

Funder(s)

Funder type

Research organisation

Funder Name

United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP) /World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

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	23/12/2008		Yes	No