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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
07/04/2005		☐ Protocol		
<b>Registration date</b> 07/06/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/01/2009	Infections and Infestations			

#### Plain English summary of protocol

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 objectives**

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

#### Health condition(s) or problem(s) studied

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

#### 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

#### Completion date

21/01/2008

# Eligibility

#### Key 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

#### Key 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 CYPD or family
- 11. History of sudden death or of prolongation of QTc interval on electrocardiogram (ECG)
- 12. Patients with cardiac arrythmia, Congestive Cardiac Failure (CCF), or bradycardia accompanied by reduced left ventricular function
- 13. Intake of drugs that prolong QTc interval

# Date of first enrolment

06/02/2004

## Date of final enrolment

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