ISRCTN86353884 https://doi.org/10.1186/ISRCTN86353884

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

Submission date	Recruitment status	[_] Prospectively registered
07/04/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2005	Completed	[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

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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

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

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