# Treatment of uncomplicated childhood malaria by artemether-lumefantrine (Coartem®) efficacy, effectiveness, safety and genotyping in Tanzania

Submission date 17/04/2007	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
Registration date	Overall study status	<ul> <li>Protocol</li> <li>Statistical analysis plan</li> </ul>	
03/05/2007	Completed	[X] Results	
Last Edited 22/03/2013	<b>Condition category</b> Infections and Infestations	Individual participant data	

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr Olumide Ogundahunsi

#### **Contact details**

Manager MIM/TDR Task Force on Malaria Research Capability Strengthening in Africa World Health Organization 20 Avenue Appia Geneva-27 Switzerland CH-1211

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers A60100

### Study information

Scientific Title

**Study objectives** The effectiveness of Coartem® would be equal to efficacy given good compliance.

**Ethics approval required** Old ethics approval format

#### Ethics approval(s)

Approval received from the ethics board of the National Institute of Medical Research Board on the 1st August 2006 (ref: NIMR/HQ/R.8a/Vol. IX/344).

**Study design** Clinical research

**Primary study design** Interventional

**Secondary study design** Single-centre

**Study setting(s)** Not specified

**Study type(s)** Treatment

Participant information sheet

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

Malaria in under five children

#### Interventions

In this clinical trial there is no intervention apart from early diagnosis and prompt treatment.

Patients will be treated with Artemether-lumefantrine (Coartem®), given either under supervision or by their parents. Treatment with Coartem® will be for three days, and the patients will be followed up on the following days:

Under supervision: follow-up on days 1, 2, 3, 7, 14, 21, 28, 35, 42, 49, 56 Drugs given by parent: follow-up on days 1, 7, 14, 21, 2, 35, 42, 49, 56 If the treatment is a clinical failure after day 14, or a parasitological failure after day 56, then the patient will again be treated for three days with Coartem®, and will be followed up on the following days:

Under supervision: follow-up on days 1, 2, 3, 7, 14, 21, 28, 35, 42 Drugs given by parent: follow-up on days 1, 7, 14, 21, 2, 35, 42

If the treatment is a clinical failure after day 14, or a parasitological failure after day 42, then the patient is treated with quinine.

Principal Investigator: Professor Zul Premji Muhimbili University College of Health Sciences Box 65011 Dar es Salaam United Republic of Tanzania Tel: +255 (0)754 304 468 Email: zpremji@muchs.ac.tz

#### Intervention Type

Drug

#### Phase

Not Specified

#### Drug/device/biological/vaccine name(s)

Artemether-lumefantrine (Coartem®)

#### Primary outcome measure

Polymerase Chain Reaction (PCR)-adjusted parasitological treatment response (cure, treatment failure) on days 14, 28, 42 and 56 after initial treatment, and on days 14, 28 and 42 after retreatment in supervised and unsupervised patients.

#### Secondary outcome measures

- 1. Occurrence of adverse events during 56 and 42 days after initial and retreatment
- 2. Recrudescence after initial and retreatment
- 3. Reinfection after initial treatment

### Overall study start date

01/03/2007

### Completion date

01/12/2009

# Eligibility

#### Key inclusion criteria

 Males or females less than five years of age with body weight greater than 5 kg
 Suffering from acute uncomplicated P. falciparum malaria confirmed by microscopy using Giemsa-stained thick film with an asexual parasite density of 2,000 to 200,000 parasites/µl
 Presenting with fever (axillary temperature equal to 37.5°C) or having a history of fever in the

#### preceding 24 hours 4. Able to ingest tablets orally (either suspended in water or un-crushed with food)

Participant type(s)

Patient

Age group Child

Upper age limit

5 Years

**Sex** Both

**Target number of participants** 360

#### Key exclusion criteria

1. Present with any of the danger signs of severe malaria

2. Signs/symptoms indicating severe/complicated malaria according to World Health

Organization (WHO) criteria (WHO definition)

3. Serious gastrointestinal disease, severe malnutrition (Weight-for-Height [W/H] less than 70%) or severe anaemia (haemoglobin less than 5 g/dl)

4. Known hypersensitivity to artemether-lumefantrine

5. Have been treated with any other drugs within eight weeks prior to screening or intend to use other drugs or biologics during the study

#### Date of first enrolment

01/03/2007

## Date of final enrolment

01/12/2009

## Locations

**Countries of recruitment** Switzerland

Tanzania

CH-1211

**Study participating centre Manager** Geneva-27 Switzerland

### Sponsor information

#### Organisation

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

#### Sponsor details

World Health Organization (WHO) 20 Avenue Appia Geneva-27 Switzerland CH-1211

**Sponsor type** Research organisation

Website http://www.who.int/tdr/diseases/malaria/mim.htm

ROR https://ror.org/01f80g185

## Funder(s)

Funder type Research organisation

**Funder Name** Multilateral Initiative on Malaria (MIM)

#### 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

### 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	01/04/2011		Yes	No
Results article	results	18/03/2013		Yes	No