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

Submission date	Recruitment status	[_] Prospectively registered
17/04/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/03/2013	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
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.

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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
1. Males or females less than five years of age with body weight greater than 5 kg
2. 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
3. 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

Study participating centre
Manager
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 (WHO)
20 Avenue Appia
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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

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