

Effectiveness and pharmacovigilance of Lapdap™ and Coartem® for the treatment of uncomplicated falciparum malaria in northeastern Tanzania

Submission date 31/03/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 31/03/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/09/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

A40744

Study information

Scientific Title

Study objectives

Lapdap™ is likely to be as effective as Coartem® in malaria management when used in an unsupervised situation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received on the 10th July 2005.

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

Interventions

Lapdap™ versus Coartem®.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lapdap™, Coartem®

Primary outcome measure

To assess the effectiveness of Lapdap™ and Coartem® through clinical and parasitological responses.

Secondary outcome measures

1. To document the frequency and type of potential drug related adverse events
2. To assess community compliance and acceptability of Lapdap™ and Coartem® use
3. To determine the prevalence and to monitor the development of dhfr/dhps gene mutations which are markers of resistance

Overall study start date

01/06/2006

Completion date

01/10/2007

Eligibility

Key inclusion criteria

1. Age between 6 and 59 months (although the lower age limit for Lapdap™ use is three months according to the label, malaria is rare among those below six months of age)
2. Weight of 5 - 16 kg
3. Presence of fever (axillary temperature greater than or equal to 37.5°C) and/or history of fever within two days
4. Uncomplicated malaria, slide-confirmed mono-infection of *P. falciparum* with 1000 - 100,000 rings/μl
5. The ability to attend follow-up visits
6. Informed consent provided by parent or guardian

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

59 Months

Sex

Both

Target number of participants

2600

Key exclusion criteria

1. Malnutrition, defined as a child whose weight-for-height is below -3 SDs or less than 70% of the median of the National Center for Health Statistics (NCHS)/World Health Organization

(WHO) normalised reference values

2. Known history of G6PD deficiency, methaemoglobin reductase deficiency, Haemoglobin M or E, or porphyria
3. Evidence of severe malaria as defined in WHO 2000
4. Hb equal to or less than 7 g/dl
5. Hypersensitivity to biguanides (e.g. proguanil, chlorproguanil) or sulphonamides such as falcidax and septrin
6. Evidence of concomitant fibrile infection
7. Treatment with antimalarial drugs within the past 14 days or 7 days with quinine (full course), proguanil, artemisinins, tetracycline doxycycline or clindamycin. Patient shall not be excluded on the basis of reported prior treatment with other anti-malarial drugs within the past 24 hours if they have a temperature and parasitemia.

Date of first enrolment

01/06/2006

Date of final enrolment

01/10/2007

Locations

Countries of recruitment

Switzerland

Tanzania

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

Industry

Funder Name

Gates Foundation (USA)

Funder Name

Glaxo SmithKline (GSK) (USA) - donating the Lapdap™ free of charge

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