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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/03/2006	**Overall study status** Completed	
Last Edited 10/09/2007	**Condition category** 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
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 defficiency, methaaemogloin 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 fancidar 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
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Switzerland
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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