ISRCTN08525528 https://doi.org/10.1186/ISRCTN08525528

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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 31/03/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 31/03/2006 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/09/2007 | Infections and Infestations | [_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Ahmed Bellah

**Contact details**
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211

## Additional identifiers

**Protocol serial number**
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

### Study type(s)
Treatment

### 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(s)
To assess the effectiveness of Lapdap™ and Coartem® through clinical and parasitological responses.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
6 months

### Upper age limit
59 months

### Sex
All

### 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)

**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

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration