

# A pragmatic trial examining the effect of compliance upon clinical effectiveness and cost effectiveness of Lapdap (CPG-DDS) when compared to sulfadoxine-pyrimethamine and Co-artem (AM-LU) for the treatment of uncomplicated falciparum malaria in Malawi

<b>Submission date</b> 20/04/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/06/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/02/2010	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

Scientific Title

**Study objectives**

This study will look at the effectiveness and cost-effectiveness of Chlorproguanil-Dapsone (CPG-DDS/Lapdap) in comparison to standard Sulfadoxine-pyrimethamine (SP) and another new antimalarial combination, artemether-lumefantrine (Co-artem) and will assess the influence of poor compliance upon the clinical response to CPG-DDS and Co-artem.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

No ethics information provided at time of registration.

**Study design**

Randomised controlled trial

**Primary study design**

Intentional

**Study type(s)**

Treatment

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

Uncomplicated malaria

**Interventions**

1. Sulfadoxine-pyrimethamine
2. Chlorproguanil-dapsone (Lapdap)
3. Artemether-lumefantrine (Co-artem)

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Sulfadoxine-pyrimethamine, Chlorproguanil-dapsone (Lapdap), Artemether-lumefantrine (Co-artem)

**Primary outcome(s)**

Investigation of the effect of incomplete compliance with three doses of CPG-DDS upon the effectiveness of CPG-DDS in an operational setting.

**Key secondary outcome(s)**

1. Comparison of the effectiveness of CPG-DDS, SP and AM-LU
2. Measurement of the degree of compliance with CPG-DDS and AM-LU
3. Observation of Adverse Events (AEs) to all three treatments
4. Modelling of the relative cost effectiveness of CPG-DDS, SP and AM-LU in this setting in Malawi

**Completion date**

31/12/2006

## Eligibility

**Key inclusion criteria**

Adults and children over the age of six months (and who weigh more than 10 kg) with uncomplicated falciparum malaria

Inclusion criteria:

1. Febrile illness
2. Asexual forms of P falciparum on blood slide

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Key exclusion criteria**

1. Severe malaria (as defined in World Health Organisation [WHO] guidelines)
2. Clinical evidence of a co-existing infection
3. Hb lower than 7 g/dl
4. Known pregnancy or positive pregnancy test (females over the age of 12)
5. Known G6PD deficiency, HbE or porphyria
6. Breast feeding mothers

**Date of first enrolment**

01/05/2004

**Date of final enrolment**

31/12/2006

## Locations

**Countries of recruitment**

United Kingdom

England

Malawi

**Study participating centre**  
Liverpool School of Tropical Medicine  
Liverpool  
United Kingdom  
L3 5QA

## Sponsor information

### Organisation

UK Government - Department for International Development (UK)

### ROR

<https://ror.org/05rf29967>

## Funder(s)

### Funder type

Government

### Funder Name

Department for International Development (UK)

## Results and Publications

### 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?
<a href="#">Results article</a>	results	26/08/2009		Yes	No