

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

Submission date 20/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/02/2010	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2004

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

Age group

Other

Sex

Both

Target number of participants

1500

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

England

Malawi

United Kingdom

Study participating centre

Liverpool School of Tropical Medicine

Liverpool

United Kingdom

L3 5QA

Sponsor information

Organisation

UK Government - Department for International Development (UK)

Sponsor details

1 Palace Street

London

United Kingdom

SW1E 5HE

M-Smith@dfid.gov.uk

Sponsor type

Government

ROR

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

Funder(s)

Funder type

Government

Funder Name

Department for International Development (UK)

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	26/08/2009		Yes	No