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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

Registration date
21/06/2005

Last Edited
10/02/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

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
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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?
Results article	results	26/08/2009		Yes	No