

Efficacy of albendazole in decreasing loa loa microfilaraemia

Submission date 04/10/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/10/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/06/2015	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Scientific

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Protocol serial number
A 60499

Study information

Scientific Title
Efficacy of albendazole in decreasing loa loa microfilaraemia

Study objectives
Two or six doses of albendazole administered at two months intervals result in significant reduction in loa loa microfilaremia and are safe and well tolerated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cameroon Comite National d'Ethique/National Ethics Committee, 23/05/2006

Study design
Randomised clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Group one: 800 mg albendazole at zero and two months (total of two doses), then placebo at four, six, eight and ten months (total of four doses)
Group two: 800 mg albendazole at zero, two, four, six, eight and ten months (total of six doses)
Group three: Placebo at zero, two, four, six, eight and ten months (total of six doses)

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)

Proportion of subjects with microfilaria count sustainably reduced by 50% from the baseline value at any time point after the first dose. A sustainable reduction by 50% is defined as a reduction to 50% of baseline LLM for at least four months.

Key secondary outcome(s)

1. Proportion of subjects with microfilaria counts reduced sustainably to less than 8100 mf/ml at any time point after first dose by microfilaria count at baseline, by gender
2. Percent reduction in microfilaria counts at each time point quantitated via the range, William geometric mean and median by treatment group, initial microfilaria level and gender
3. Evolution of loa parasitemia with time in each treatment group analysed via General Linear Model

Completion date

30/06/2008

Eligibility**Key inclusion criteria**

1. 18 to 65 year old male or female.
2. Loa Loa Microfilaremia (LLM) greater than 15000 mf/ml as determined by calibrated blood smear
3. Do not plan on moving out of the area over the next two years
4. Given informed consent (written, witnessed, signed or thumb printed)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Treatment with a benzimidazole during the last 12 months
2. Self-reported allergy to benzimidazoles
3. Pregnancy, assessed by urine pregnancy test (Beta-Human Chorionic Gonadotropin [β -HCG]) before each treatment in all women of child-bearing potential
4. Clinical signs and symptoms and laboratory evidence of intestinal helminths
5. Any serious underlying medical condition

6. Past or current history of neurological or neuropsychiatric disorders
7. Clinical and/or laboratory evidence of significant liver disease, kidney disease or anaemia or any other condition that in the investigator's judgment should exclude the subject from the study

Date of first enrolment

30/11/2006

Date of final enrolment

01/04/2007

Locations

Countries of recruitment

Cameroon

Switzerland

Study participating centre

Special Programme for Research & Training in Tropical Diseases (TDR)

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

GlaxoSmithKline (GSK) (International)

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

World Bank Group

Alternative Name(s)

World Bank, The World Bank, Grupo Banco Mundial, Groupe Banque Mondiale, , Група Всесвітнього банку, WBG

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United States of America

Funder Name

Bill and Melinda Gates Foundation (BMGF) (USA)

Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary