

# Efficacy of albendazole in decreasing loa loa microfilaraemia

<b>Submission date</b> 04/10/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/10/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/06/2015	<b>Condition category</b> 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

**Type(s)**  
Scientific

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## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**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**

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 measure**

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.

**Secondary outcome measures**

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

**Overall study start date**

30/11/2006

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

60

**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 [ $\beta$ -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)

**Sponsor details**

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

**Sponsor type**

Research organisation

**Website**

<http://www.who.int>

**ROR**

<https://ror.org/01f80g185>

**Funder(s)****Funder type**

Industry

**Funder Name**

GlaxoSmithKline (GSK) (International)

**Alternative Name(s)**

GlaxoSmithKline plc., GSK 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, Banco Mundial, Groupe Banque Mondiale, Banque Mondiale, , Группа Всемирного банка, , 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, 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**

African Programme for Onchocerciasis Control (APOC) (Burkina Faso)

## 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