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Efficacy of albendazole in decreasing loa loa microfilaraemia

Submission date	Recruitment status	[X] Prospectively registered
04/10/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/06/2015	Infections and Infestations	[_] 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 [ß-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