

# Clinical trials of drugs for onchocerciasis: a randomised, single-ascending-dose, ivermectin-controlled, double-blind, safety, tolerability, pharmacokinetic, and efficacy study of orally administered moxidectin in subjects with *Onchocerca volvulus* infection (Ghana)

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| <b>Submission date</b><br>15/04/2005   | <b>Recruitment status</b><br>No longer recruiting        | <input checked="" type="checkbox"/> Prospectively registered |
| <b>Registration date</b><br>07/06/2005 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                            |
| <b>Last Edited</b><br>20/02/2019       | <b>Condition category</b><br>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

ClinicalTrials.gov (NCT)  
NCT00300768

**Protocol serial number**

980819 (B)

## **Study information**

**Scientific Title**

Clinical trials of drugs for onchocerciasis: a randomised, single-ascending-dose, ivermectin-controlled, double-blind, safety, tolerability, pharmacokinetic, and efficacy study of orally administered moxidectin in subjects with *Onchocerca volvulus* infection (Ghana)

**Study objectives**

Orally administered moxidectin is safe and well tolerated in subjects infected with *Onchocerca volvulus* and leads to long term suppression of skin microfilaria.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Ghana Health Service Ethical Review Committee, 24/08/2006
2. World Health Organization (WHO) Ethics Review Committee, 28/06/2006

**Study design**

Randomised, single ascending dose, active-control, double-blind trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Onchocerciasis

**Interventions**

Single dose of moxidectin of 2 mg, 4 mg or 8 mg, or ivermectin at the approved dose.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Moxidectin, ivermectin

**Primary outcome(s)**

Data on safety and tolerability of a single oral dose of moxidectin (2, 4, or 8 mg)

**Key secondary outcome(s)**

Skin microfilaria levels up to 18 months post treatment

**Completion date**

29/11/2009

**Eligibility**

**Key inclusion criteria**

1. Ivermectin-naïve men and women otherwise healthy, with *O. volvulus* infection
2. Informed consent
3. Aged 18 to 60 years
4. Body weight more than or equal to 40 kg for women, or more than or equal to 45 kg for men
5. Non-pregnant, non-lactating, willing to use contraception during the first 150 days after treatment
6. Normal medical history, physical examination, Electrocardiogram (ECG) and lab results
7. Adequate hematologic, renal and hepatic functions
8. Skin microfilarial density within the required range for the cohort

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Participation in any studies other than purely observational ones within four weeks before test article administration
2. Any vaccination within four weeks before test article administration
3. Acute infection requiring therapy within the last ten days before test article administration
4. Any medication (with the exception of medication required to treat any reactions during the screening fluorescein angiography (chlorpheniramine) or paracetamol) or herbal preparation within ten days prior to test article administration or any condition currently requiring regular medication
5. History of drug or alcohol abuse or regular use of more than three cigarettes/day, use of alcohol or other drugs of abuse within 72 hours before test article administration
6. Blood donation within eight weeks before study entry
7. Clinically significant ECG abnormalities, or history of cardiac abnormalities, or past or current history of neurological or neuropsychiatric disease or epilepsy
8. Ocular onchocerciasis
9. Hyperactive onchodermatitis
10. Antifilaria therapy within previous five years

11. Coincidental infection with Loa Loa
12. Orthostatic hypotension
13. Female patient with contraindication to DepoMedroxyProgesterone Acetate (DMPA) if not on Norplant

**Date of first enrolment**

01/09/2006

**Date of final enrolment**

30/06/2008

## Locations

**Countries of recruitment**

Ghana

Switzerland

**Study participating centre**

**World Health Organization**

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**

Research organisation

**Funder Name**

United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP) /World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

# 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 26/06/2014   | 20/02/2019 | Yes            | No              |