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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)

Submission date 15/04/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/06/2005	**Overall study status** Completed	
Last Edited 20/02/2019	**Condition category** Infections and Infestations	

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?
Results article	results	26/06/2014	20/02/2019	Yes	No