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Doxycycline treatment to eliminate Onchocerca volvulus worms that respond poorly to ivermectin

Submission date	Recruitment status	[_] Prospectively registered
19/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/07/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

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Type(s)
Scientific

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Additional identifiers

Protocol serial number
INCO-CT-2006-032321

Study information

Scientific Title
Doxycycline treatment to eliminate Onchocerca volvulus worms that respond poorly to ivermectin: a double-blind randomised placebo-controlled trial

Acronym
SCOOTT (Sustainable Control of Onchocerciasis Today and Tomorrow)

Study objectives
Proof that doxycycline treatment is safe, tolerable and an effective alternative for patients in whom ivermectin has failed to clear microfilariae (potentially due to worm resistance to ivermectin).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee on Human Research Publication and Ethics, Kwame Nkrumah University of Science and Technology, 15/03/2007

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Onchocerciasis (river blindness)

Interventions
100 mg/day oral doxycycline or matching placebo for 6 weeks.

Volunteers for this study are recruited, based on the inclusion and exclusion criteria, and treated directly in their villages (along the Pru and Lower Black Volta river basins). The study drugs are to be distributed ad personam by the research-staff and drug intake is monitored on a daily basis for 6 weeks.

To assess the skin microfilarial load, skin biopsies are taken pre-treatment, 12 months and 20 months after treatment. Nodulectomies to assess the worm vitality and embryogenesis are performed 20 months after the start of drug administration. Onchocercomas will be removed under local anaesthesia in the hospital.

Patients are kept in hospital for one day after operation before discharge to be observed by the surgeon. Wound dressing will continue in the villages until all wounds are healed.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Proportion of sterile or dead female O. volvulus worms in nodules from doxycycline-treated onchocerciasis patients, measured 20 months after the start of drug administration

Key secondary outcome(s))
Reduction or absence of microfilariae in the skin, measured 20 months after the start of drug administration

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Males and females between 18 - 50 years
2. Good general health without any clinical condition requiring long-term medication
3. Clinical manifestation of onchocerciasis assessed by skin biopsies and palpation (at least one onchocercoma)
4. Minimum body weight 40 kg

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy (if not obvious all women are tested by dipstick chemistry: beta-human chorionic gonadotropin [BhCG])
2. Currently breast-feeding
3. Evidence of clinically significant neurological, cardiac, pulmonary, hepatic, rheumatological, or renal disease by history, physical examination, and/or laboratory tests
4. Behavioural, cognitive or psychiatric disease that, in the opinion of the investigator, affects the ability of the volunteer to understand and cooperate with the study protocol
5. Laboratory evidence of liver disease (aspartate aminotransferase [AST], alanine aminotransferase [ALT] and/or gamma-glutamyl transferase (GGT) greater than 1.25 times the upper limit of normal of the testing laboratory)
6. Laboratory evidence of renal disease (serum creatinine greater than 1.25 times the upper limit of normal of the testing laboratory)
7. Other condition that, in the opinion of the investigator, would jeopardise the safety or rights of a volunteer participating in the trial or would render the subject unable to comply with the protocol
8. Volunteer has abused alcohol or illicit drugs during the past 6 months by history
9. History of severe allergic reaction or anaphylaxis
10. Intolerance to doxycycline

Date of first enrolment
01/06/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Germany

Ghana

Study participating centre
University of Bonn
Bonn
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Sponsor information

Organisation
European Commission (Belgium)

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium) (ref: INCO-CT-2006-032321)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/08/2015		Yes	No