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Anti-wolbachia treatment of onchocerciasis in an area co-endemic for loiasis

Submission date	Recruitment status	[_] Prospectively registered
12/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/04/2010	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC-A4-CT 2002-10051 WP2C

Study information

Scientific Title

Acronym
WOLBACHFIL

Study objectives
Anti-wolbachia (doxycycline) treatment or anti-wolbachia treatment combined with standard anti-filarial treatment (ivermectin) has superior efficacy compared with standard anti-filarial treatment of onchocerciasis.
Doxycycline is a suitable and efficacious treatment for onchocerciasis in patients co-infected with loiasis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Onchocerciasis, loiasis

Interventions
200 mg/day oral doxycycline or matching placebo for six weeks
150 mg/kg oral single dose ivermectin or matching placebo for four months post commencement of doxycycline treatment

Intervention Type
Drug

Phase

Not Specified

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

Primary outcome measure
Sustained amicrofilaridermia in doxycycline or doxycycline and ivermectin-treated patients compared with ivermectin treated-patients assessed by levels of microfilaridermia in skin biopsies at 4, 12 and 21 months

Secondary outcome measures
Macrofilaricidal (curative) effects of doxycycline treatment assessed by ultrasonography, histology and ribonucleic acid (RNA) levels of adult worms in onchocercomas at 21 months

Overall study start date
01/07/2003

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. Mean microfilaridermia >10 mf/mg
2. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Body weight <40 kg
2. Ages <15 or >50
3. Patients receiving medication for chronic illness
4. Anti-filarial treatment in the last year
5. Alcohol or drug abuse
6. Abnormal renal or hepatic blood chemistry
7. Pregnancy
8. Lactation

Date of first enrolment
01/07/2003

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
Cameroon

England

United Kingdom

Study participating centre
Liverpool School of Tropical Medicine
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Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

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Sponsor type
University/education

Website
http://www.liv.ac.uk/lstm

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
European Commission (EC) (Contract IC-A4-CT 2002-10051)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/04/2010		Yes	No