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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

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

Completion date

31/03/2005

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Cameroon

Study participating centre
Liverpool School of Tropical Medicine
Liverpool

United Kingdom
L3 5QA

Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

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, 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	13/04/2010		Yes	No