

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

Submission date 12/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/04/2010	Condition category 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

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

Primary study design

Interventional

Study design

Randomised double blind placebo controlled trial

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