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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
12/01/2006		☐ Protocol		
Registration date 24/01/2006	Overall study status Completed	Statistical analysis plan		
		[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

#### Contact name

Dr Mark Taylor

#### Contact details

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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

## 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
Liverpool
United Kingdom
L3 5QA

# Sponsor information

## Organisation

Liverpool School of Tropical Medicine (UK)

## Sponsor details

Pembroke Place Liverpool England United Kingdom L3 5QA +44 (0)151 7053281 hemingway@liv.ac.uk

## 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, Εвροπεйската 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