# Antibiotic targeting of Wolbachia endosymbiotic bacteria as a new approach to the treatment of filarial (Brugia malayi) infection and disease

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
21/09/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
31/10/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
25/09/2009	Infections and Infestations			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Prof Maria Yazdanbakhsh

#### Contact details

Department of Parasitology Leiden University Medical Center Albinusdreef 2 Leiden Netherlands 2333 ZA

## Additional identifiers

#### Protocol serial number

EU contract ICA4-CT-2002-10051

# Study information

Scientific Title

#### Acronym

**WOLBACHFIL** 

#### Study objectives

Filarial infection and disease is associated with episodes of acute and chronic inflammation that can lead to lymphangitis, hydrocele and elephantiasis. Wolbachia are symbiotic endobacteria in filarial nematodes that have recently emerged as targets for improved chemotherapy of filariasis by tetracycline antibiotics, with potential to close the gap left open in current mass treatment programs.

#### The purpose of this project is:

- 1. To define if anti-Wolbachia treatment is effective to deplete Wolbachia from Brugia malayi, and, that in combination with Diethylcarbamazine (DEC), leads to a sustained amicrofilaraemia in brugian filariasis
- 2. To determine if anti-Wolbachia treatment leads to reduced adverse reactions to filarial chemotherapy

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethical clearance has been obtained from Liverpool School of Tropical Medicine Research Ethics Committee dated 06/12/2001 (reference number: 01.74) for whole EU contract and also from the Committee of the Medical Ethics of the Faculty of Medicine, University of Indonesia, Jakarta, Indonesia, dated 12/08/2002 (reference number: 65/ PT01.FK/Etik/2002).

#### Study design

Randomised double-blind placebo-controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Filarial infection and disease from Brugia malayi

#### Interventions

100 mg/kg doxycycline or matching placebo for six weeks, 6 mg/kg oral DEC plus 400 mg Albendazole or matching placebo for four months post-commencement of doxycycline treatment.

#### **Intervention Type**

Drug

#### Phase

**Not Specified** 

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

Doxycycline, diethylcarbamazine and albendazole

#### Primary outcome(s)

Sustained amicrofilaraemia in doxycycline or doxycycline and DEC and Albendazole treated patients compared with DEC and Albendazole treated patients as assessed by levels of microfilariae in night blood at two, four and 12 months.

#### Key secondary outcome(s))

Reduction in adverse reaction to DEC and Albendazole treatment.

#### Completion date

01/09/2004

## Eligibility

#### Key inclusion criteria

- 1. All male and female subjects, who have given informed consent were evaluated
- 2. Mean microfilariae more than 5 Mf/ml

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

ΔII

#### Key exclusion criteria

- 1. Aged less than 12 years
- 2. Patients receiving medication for chronic illness
- 3. Anti-filarial treatment in the last year
- 4. Alcohol or drug abuse
- 5. Pregnancy
- 6. Lactation
- 7. Abnormal renal or hepatic blood chemistry

#### Date of first enrolment

01/03/2003

#### Date of final enrolment

01/09/2004

## Locations

#### Countries of recruitment

Indonesia

Netherlands

Study participating centre
Department of Parasitology
Leiden
Netherlands
2333 ZA

# Sponsor information

## Organisation

European Commission (Belgium)

#### **ROR**

https://ror.org/00k4n6c32

# Funder(s)

## Funder type

Government

#### **Funder Name**

European Commission (EC) contract (reference number: ICA4-CT-2002-10051)

# **Results and Publications**

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	01/05/2008		Yes	No