

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

Submission date

21/09/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

31/10/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

25/09/2009

Condition category

Infections and Infestations

☐ Individual participant data

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).

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

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

All

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