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

Recruitment status	Prospectively registeredProtocol	
No longer recruiting		
Overall study status	Statistical analysis plan	
Completed	[X] Results	
Condition category	[] Individual participant data	
	No longer recruiting Overall study status Completed	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

Reduction in adverse reaction to DEC and Albendazole treatment.

Overall study start date

01/03/2003

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

Age group

Not Specified

Sex

Both

Target number of participants

150

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)

Sponsor details

European Commission Research Directorate-General Rue de la Loi 200 Bruxelles Belgium B-1049 +32 (0)2 299 1111 rtd-inco-projects@cec.eu.int

Sponsor type

Government

Website

http://www/europa.eu.int

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

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	01/05/2008		Yes	No