ISRCTN37962059 https://doi.org/10.1186/ISRCTN37962059

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

Registration date
31/10/2006

Last Edited
25/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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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