ISRCTN12273637 https://doi.org/10.1186/ISRCTN12273637

Targeting on the values of Wolbachia endosymbionts as novel feasible anti-filarial chemotherapeutic approach to prevent/reduce /clear disease in lymphatic filariasis and interrupt transmission in endemic communities of Tanzania

Submission date 26/01/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/03/2009	**Overall study status** Completed	
Last Edited 05/03/2009	**Condition category** Infections and Infestations	

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
N/A

Study information

Scientific Title
Targeting on the values of Wolbachia endosymbionts as novel feasible anti-filarial chemotherapeutic approach to prevent/reduce/clear disease in lymphatic filariasis and interrupt transmission in endemic communities of Tanzania: a randomised double-blind placebo-controlled trial

Study objectives
Wolbachia endosymbionts bacteria are associated with inflammatory process in their human-host and filarial nematode causing overt clinical disease. However, the use of antibiotics with macrofilaricidal activity (doxycycline) that kills adult worms, might prevent or halt/cure/clear clinical disease such as lymphoedema (LE), acute dermatoadenolymphangitis (ADLA) or acute filarial fevers with lymphangitis (AFL). In the present study, it will be investigated whether patients with ongoing infection (i.e., who are positive for circulating filarial antigen [CFA]) will benefit more, in the same way or less than patients without ongoing infection (i.e. CFA negative) but remaining pathology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Research Coordinating Committee of Tanzania approved on 11th November 2005 (ref: NIMR/HQ/R.8a/vol.IX/403)

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Wuchereria bancrofti lymphoedema stage I - V

Interventions
45 individuals with circulating filarial antigen positive (CFA) and 45 individuals without circulating filarial antigen in their blood will be randomised to:
1. 200 mg/day doxycycline for 6 weeks
2. Placebo for 6 weeks

Contact details for co-investigator:
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Intervention Type
Drug

Phase
Phase II

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

Primary outcome measure
1. Proportion of patients whose lymphoedema is reduced in size or cured
2. Proportion of acute filarial fevers and acute dermatoadenolymphangitis episodes or subclinical episodes prevented or reduced or halted during the trial period
3. Levels of CFA reduced or cleared
4. Levels of vascular endothelial growth factors (VEGFs) and pro-inflammatory immunological responses in plasma pre-post treatment in different stages of LE individuals

Secondary outcome measures
1. The length of time taken for LE to change in size or cured or reappear again
2. The levels of anti-Wolbachia surface protein antibodies response at pre-post treatment
3. Tolerability of the anti-Wolbachia agent (antibiotic-doxycycline) (drug adverse events)

Overall study start date
27/09/2008

Completion date
21/11/2010

Eligibility

Key inclusion criteria
1. Age range 18 - 68 years
2. Males and females
3. Diagnosed clinically to have lymphoedema stages I - V
4. Permanent residents in the study area
5. May be microfilaraemia positive or negative

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90 individuals with lymphoedema

Key exclusion criteria
1. Children and pregnant women
2. Chronic liver, kidney, cardiac, central nervous system disease
3. Allergy to the trial drugs
4. Previous history of using anti-filarial drugs, e.g. ivermectin, albendazole, diethylcarbamazine
5. Past history of taking anti-geohelminthics, e.g. mebendazole, and antibiotics such as tetracycline or rifampicin in the last six months

Date of first enrolment
27/09/2008

Date of final enrolment
21/11/2010

Locations

Countries of recruitment
Germany

Tanzania

Study participating centre
Director, MD
Bonn

Germany
53105

Sponsor information

Organisation
Volkswagen Foundation (VolkswagenStiftung) (Germany)

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Sponsor type
Research organisation

Website
http://www.volkswagenstiftung.de

ROR
https://ror.org/03bsmfz84

Funder(s)

Funder type
Research organisation

Funder Name
Volkswagen Foundation (VolkswagenStiftung) (Germany)

Alternative Name(s)
VolkswagenStiftung

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

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