

# 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

<b>Submission date</b> 26/01/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/03/2009	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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 dermatadenolymphangitis (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

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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 dermatadenolymphangitis 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)

### Sponsor details

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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