# Wolbachia endobacteria in filarial infections - exploring their usefulness as targets for novel chemotherapies that are anti-filarial and improve hydrocele

Submission date	Recruitment status	Prospectively registered
19/01/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
13/02/2009	Completed	☐ Results
Last Edited	Condition category	Individual participant data
13/02/2009	Infections and Infestations	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Achim Hoerauf** 

#### Contact details

Institute of Medical Microbiology, Immunology and Parasitology University of Bonn, Faculty of Medicine Sigmund Freud Str. 25 Bonn Germany 53105 +49 (0)228 287 15675 hoerauf@microbiology-bonn.de

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

1/81 306

# Study information

#### Scientific Title

Wolbachia endobacteria in filarial infections - exploring their usefulness as targets for novel chemotherapies that are anti-filarial and improve hydrocele: a randomised double blind placebocontrolled trial

#### **Study objectives**

Filarial infections belong to the major diseases in sub-Saharan Africa and are strongly associated with poverty. At present, World Health Organization (WHO) led control activities in Africa mainly rely on mass administration of microfilaricidal drugs, with a measure of success. However, it has become clear that new, complementary therapies, ideally being macrofilaricidal, must be developed for sustainable control.

In lymphatic filariasis (LF), there is the additional need to deliver new therapies for lymphatic pathology, i.e. lymphoedema and urogenital pathology such as hydrocele and lymphocele, which are not targeted by current mass drug administrations. Depletion of Wolbachia essential endosymbionts of filariae with doxycycline, an approach established by our group, resulted in macrofilaricidal activity in LF. The present study hypothesises that Wolbachia also play a major role in inducing and maintaining lymphatic pathology, and that doxycycline may therefore improve hydrocele.

#### The aim of this project is:

- 1. To analyse to what extent hydrocele is caused by Wolbachia. To this, the Wolbachia-depleting antibiotic doxycycline will be administered and alterations of hydrocele size will be determined.
- 2. To analyse the role of Wolbachia in the systemic immune responses in hydrocele patients, by comparing immune responses before and after Wolbachia depletion

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

The Committee on Human Research Publication and Ethics, Kwame Nkrumah University of Science and Technology, Kumasi, Ghana approved on 25th November 2005

# 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

Lymphatic filariasis (Wuchereria bancrofti)

#### **Interventions**

Study drugs and treatment regimens:

- 1. 200 mg/day doxycycline for 6 weeks
- 2. Placebo for 6 weeks

Contact details for Joint Principal Investigators:

Professor Ohene Adjei

Kwame Nkrumah University of Science and Technology (KNUST), and Kumasi Centre of

Collaborative Research (KCCR)

**University Post Office** 

Kumasi, Ghana

Tel: + 233 51 60351 Fax: + 233 51 62017

E-mail: oadjei@africaonline.com

Dr Alexander Yaw Debrah

Kwame Nkrumah University of Science and Technology (KNUST), and Kumasi Centre of Collaborative Research (KCCR)

University Post Office

Kumasi, Ghana

Tel: + 233 51 60351 Fax: + 233 51 62017

E-mail: yadebrah@yahoo.com

#### Intervention Type

Drug

#### Phase

Phase II

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

Doxycycline

#### Primary outcome measure

Reduction in size of clinical and sub-clinical hydrocele, measured pre-treatment as well as 12 months and 24 months after the start of drug administration.

#### Secondary outcome measures

- 1. Reduction in the stage of supratesticular dilation of scrotal lymphatic vessels, measured pretreatment as well as 12 months and 24 months after the start of drug administration
- 2. Reduction in circulating filarial antigen levels as a measure of macrofilaricidal effect of

doxycycline, measured pre-treatment as well as 3 months, 12 months and 24 months after the start of drug administration

3. Change in systemic immune responses, measured pre-treatment as well as 3 months, 12 months and 24 months after the start of drug administration

## Overall study start date

01/12/2005

#### Completion date

30/03/2009

# **Eligibility**

### Key inclusion criteria

- 1. Men between 18 60 years
- 2. Resident in the village for five years or more
- 3. Evidence of hydrocele assessed by physical examination and ultrasonography
- 4. Good general health without any clinical condition requiring long-term medication
- 5. Minimum body weight 40 kg

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Male

# Target number of participants

76

#### Key exclusion criteria

- 1. Evidence of clinically significant neurological, cardiac, pulmonary, hepatic, rheumatological, or renal disease by history, physical examination, and/or laboratory tests
- 2. Behavioural, cognitive or psychiatric disease that, in the opinion of the investigator, affects the ability of the volunteer to understand and cooperate with the study protocol
- 3. Laboratory evidence of liver disease (aspartate aminotransferase [AST] alanine aminotransferase [ALT] and/or gamma-glutamyl transferase (gGT) greater than 1.25 times the upper limit of normal of the testing laboratory)
- 4. Laboratory evidence of renal disease (serum creatinine greater than 1.25 times of the upper limit of normal of the testing laboratory)
- 5. Other conditions that, in the opinion of the investigator, would jeopardise the safety or rights of a volunteer participating in the trial or would render the subject unable to comply with the protocol

- 6. Volunteer has abused alcohol or illicit drugs during the past 6 months by history
- 7. History of severe allergic reaction or anaphylaxis
- 8. Intolerance to doxycycline

#### Date of first enrolment

01/12/2005

#### Date of final enrolment

30/03/2009

# Locations

#### Countries of recruitment

Germany

Ghana

# Study participating centre Institute of Medical Microbiology, Immunology and Parasitology

Bonn Germany 53105

# **Sponsor information**

## Organisation

Volkswagen Foundation (VolkswagenStiftung) (Germany)

#### Sponsor details

c/o Dr Detlev Hanne
Division Natural and Engineering Sciences, Medicine
Kastanienallee 35
Hannover
Germany
30519
+49 (0)511 8381 0
info@volkswagenstiftung.de

#### Sponsor type

Research organisation

#### Website

http://www.volkswagenstiftung.de

#### **ROR**

# Funder(s)

## Funder type

Research organisation

#### **Funder Name**

Volkswagen Foundation (VolkswagenStiftung) (Germany) (ref: 1/81 306)

### 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