ISRCTN19748404 https://doi.org/10.1186/ISRCTN19748404

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

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Additional identifiers

Protocol serial number
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 placebo-controlled 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

Study type(s)
Treatment

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

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Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
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.

Key secondary outcome(s))
1. Reduction in the stage of supratesticular dilation of scrotal lymphatic vessels, measured pre-treatment 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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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
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Sponsor information

Organisation
Volkswagen Foundation (VolkswagenStiftung) (Germany)

ROR
https://ror.org/03bsmfz84

Funder(s)

Funder type
Research organisation

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

Alternative Name(s)
VolkswagenStiftung, The Volkswagen Foundation

Funding Body Type
Private sector organisation

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

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary