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Antibiotic targeting of wolbachia endosymbiotic bacteria as a new approach to the treatment of filarial (Onchocerca Volvulus) infection and disease

Submission date
02/06/2006

Recruitment status
No longer recruiting

Registration date
06/07/2006

Overall study status
Completed

Last Edited
09/05/2019

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
EC contract IC-A4-CT 2002-10051 (WP 1)

Study information

Scientific Title
Antibiotic targeting of wolbachia endosymbiotic bacteria as a new approach to the treatment of filarial (Onchocerca Volvulus) infection and disease

Acronym
WOLBACHFIL

Study objectives
Wolbachia are symbiotic endobacteria in filarial nematodes that have recently emerged as targets for improved chemotherapy of filariasis by tetracycline antibiotics, with the potential to close the gap left open in current mass treatment programs.
The purpose of this project is:
1. To define the minimum regimen of anti-wolbachia drug doxycycline needed to achieve depletion of wolbachia and a complete sterilization of adult female worms in onchocerciasis, as well as sustained amicrofilaraemia in combination with ivermectin
2. To verify or reject the macrofilaricidal effect of doxycycline
3. To investigate the role of wolbachia-release by microfilaricidal therapy in the induction of side effects. The study will allow us to assess the role of wolbachia in pathogenesis and as targets for the long-needed second punch for sustained amicrofilaraemia and interruption of transmission.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval has been obtained from the Liverpool School of Tropical Medicine Research Ethics Committee dated 06/12/2001, reference number: 01.74 for the whole EC contract and also from the Committee on Human Research Publications and Ethics, School of Medical Sciences, University of Science and Technology, Kumasi, Ghana dated 20/01/2003)

Study design
Randomised, double-blind, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Onchocerciasis (river blindness)

Interventions
200 mg/day Oral doxycycline or matching placebo for six weeks versus four weeks; 150 mg/kg oral single dose ivermectin or matching placebo four months post-commencement of doxycycline treatment.

Added as of 13/04/2007:
200 was an erroneous copy-paste from an older version of the study protocol which got down-scaled by the Ethics Committee during the process of ethical clearance - the final study protocol version contained three treatment arms with 25 participants each, therefore a total number of 75 participants.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Sustained amicrofilaraemia in doxycycline- and ivermectin-treated patients compared with ivermectin-treated patients as assessed by levels of microfilaridermia in skin biopsies at 5,15 and 21 months
2. Macrofilaricidal (curative) effects of doxycycline treatment as assessed by immunohistology, polymerase chain reaction (PCR) and ultrasonography at 5, 15 and 21 months

Secondary outcome measures
Reduction in adverse reaction to ivermectin treatment

Overall study start date
01/08/2003

Completion date
30/11/2005

Eligibility

Key inclusion criteria
All male or female subjects, aged 18-50 years, who have given informed consent (written or thumb print) were evaluated. Minimum body weight criteria is >40 kg. Participants were then included only if they met the following criteria:
1. Normal renal and hepatic laboratory profiles for aspartate aminotransferase (AST) (0-40 IU/l), alanine aminotransferase (ALT) (0-45 IU/l)
2. Creatinine 53-126 µmol/l as measured by dipstick chemistry

3. More than two palpable onchocercomas
4. Microfilarial (Mf) counts >10 Mf/mg (skin biopsies)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
200 (75 as of 13/04/07 - see interventions field)

Total final enrolment
67

Key exclusion criteria
1. Pregnancy (pregnancy test)
2. Lactation
3. Intolerance to ivermectin or doxycycline
4. Chronic diseases
5. Alcohol or drug abuse
6. Anti-filarial therapy within the last two years

Date of first enrolment
01/08/2003

Date of final enrolment
30/11/2005

Locations

Countries of recruitment
Germany

Ghana

Study participating centre

Director of the Institute of Medical Microbiology Immunology and Parasitology (IMMIP)
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Sponsor information

Organisation
European Commission (Belgium)

Sponsor details
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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 (Belgium) (ref: IC-A4-CT2002-10051)

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	01/09/2008	09/05/2019	Yes	No