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Evaluation of the impact of large scale, community directed delivery of doxycycline for the treatment of onchocerciasis

Submission date
11/05/2011

Recruitment status
No longer recruiting

Registration date
10/08/2011

Overall study status
Completed

Last Edited
05/02/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Onchocerciasis, also known as river blindness, is a tropical disease caused by a parasitic worn called Onchocerca volvulus. It is spread through the bite of a blackfly, an insect which is common near fast-flowing streams and rivers in countries with a tropical climate (such as sub-Saharan Africa). As well as affecting vision, the skin of sufferers can become discoloured giving a “leopard skin” appearance, as well as developing hundreds of lumps (nodules) covering their body’s. Over time, the infection causes long-lasting skin damage and blindness, however if it is treated early then this can be prevented. A new treatment for onchocerciasis has been developed using the antibiotic, doxycycline, which works by removing a bacteria that works together with the parasitic worms (symbiont). Early studies have shown that treatment with doxycycline is more effective than the current standard treatment (ivermectin), which needs to be given for at least 6 months to kill the adult worms. Although treating the injection with doxycycline is much shorter, at around 6 weeks, it can have unwanted side effects and so it is not known whether patients will complete the course (compliance). The aim of this study is to find out how effective doxycycline is four years after treatment, and if this is related to compliance rate during treatment.

Who can participate?
In stage one of the study, adults over 19 years of age, who have received previous treatment with doxycycline are included. In stage two of the study, the participants from stage one who still have at least one nodule left after treatment are included.

What does the study involve?
In the first stage of the study, skin biopsies (samples) are taken from the hip area of all participants in order to examine it under a microscope for the presence of baby worms (microfilarae). Participants also have their entire bodies felt (palpated) in order to see if there are any nodules (lumps) caused by the infection. In the second stage of the study, further skin biopsies are taken. The presence of nodules is also checked for using an ultrasound machine (scanner which uses high-frequency sound waves).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study is run from the Liverpool School of Tropical Medicine and takes place in Cameroon

When is the study starting and how long is it expected to run for?
May 2011 to December 2011

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Professor Mark J Taylor
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Study website
http://www.a-wol.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Grant ref 39284

Study information

Scientific Title

Evaluation of the impact of large scale, community directed delivery of doxycycline for the treatment of onchocerciasis: the Anti-Wolbachia (A-WOL) trial

Acronym
A-WOL CDTD

Study objectives
To evaluate the efficacy of community directed delivery of doxycycline Mass Drug Administration (MDA), at the community level and in patients with onchocerciasis. This will serve to:
1. Evaluate the efficacy of doxycycline MDA followed by ivermectin MDA four years after delivery and validate compliance rate of a phase III implementation trial
2. Evaluate whether ultrasonography of palpable nodules to detect parasite motility can be used to monitor and evaluate macrofilariacidal activity after doxycycline MDA

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Reserach Ethics Commitee, Liverpool School of Tropical Medicine (LSTM) approved on 27th April 2011
2. Institutional Review Board of the Medical Research Station of Kumba approved on 31st March 2011

Study design
Single-blind evaluation of a phase III implementation trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Onchocerciasis (Onchocerca volvulus)

Interventions
The treatment was carried out in a previous feasibility trial of community delivered doxycycline treatment. The drug given in the feasibility trial was doxycycline at 100mg/day, once a day for 6 weeks. The participants were then treated annually with a standard dose of ivermectin (Mectizan®) as per annual mass drug administration for the following 2 years.

Stage 1
1. Skin biopsies (two skin snips from the iliac crests performed at the same time) will be taken to assess the presence and load of microfilarae in the skin following prior disinfection of the skin
2. Body palpation will be carried out and the presence, number and location of palpable nodules recorded on the case report form

Stage 2:
1. Skin biopsies (two skin snips from the iliac crests performed at the same time) will be taken to assess the presence and load of microfilarae in the skin following prior disinfection of the skin
2. All accessible palpable nodules will be examined by ultrasonography
3. The presence of motile adult worms will be recorded by digital video recorder and on the case report form

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
To evaluate the efficacy of doxycycline MDA followed by ivermectin MDA four years after delivery, at the community level (Stage 1) and known infected patients (Stage 2) and validate compliance rate of phase III implementation trial

Secondary outcome measures
To evaluate whether ultrasonograpy of palpable nodules to detect parasite motility can be used to monitor and evaluate macrofilaricidal activity after doxycycline MDA

Overall study start date
13/05/2011

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Stage 1
1. Participants of both sexes aged 19 years or above
2. Received either 6 weeks of doxycycline MDA followed by one or two rounds of annual ivermectin MDA or one or two rounds of annual ivermectin MDA alone
3. Willingness to participate in the study by signing the informed consent form

Stage 2
1. Participants of both sexes aged 19 years or above
2. Received either 6 weeks of doxycycline MDA followed by one or two rounds of annual ivermectin MDA or one or two rounds of annual ivermectin MDA alone

3. Presence of a minimum of one onchocercoma detected by palpation
4. Good general health without any clinical condition under treatment with long term medication
5. Willingness to participate in the study by signing the informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600 for stage 1 and 82 for stage 2

Key exclusion criteria
For stages 1 and 2:
1. Ivermectin intake since June 2010 (date of last ivermectin MDA)
2. Intake of antibiotics (tetracyclines or rifamycins) for longer that 2 weeks since June 2007
3. Behavioural, cognitive or psychiatric diseases that in the opinion of the trial clinician affects the ability of the participant to understand and cooperate with the study protocol
4. Any other condition that, in the opinion of the investigator (trial clinician), would risk the safety or rights of the participants in the trial or would render the subject unable to comply with the protocol

Date of first enrolment
13/05/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Cameroon

England

United Kingdom

Study participating centre
Liverpool School of Tropical Medicine
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Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

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Sponsor type
University/education

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ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (USA) (Grant ref: 39284)

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

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

Location
United States of America

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