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Lake Victoria Island Intervention Study on Worms and Allergy-related diseases

Submission date
05/09/2012

Recruitment status
No longer recruiting

Registration date
07/09/2012

Overall study status
Completed

Last Edited
24/07/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Worm infections have important effects on human health, especially schistosomiasis, a parasitic worm infection transmitted through contact with water. Schistosomiasis can cause liver disease and problems with the gut and bladder. It may also cause anaemia and poor growth, and poor performance at school. On the other hand there is evidence that worm infections may protect against allergy and asthma. The aim of this study is to weigh the benefits of intensive (versus standard) intervention against worms, including schistosomiasis, versus the disadvantages in terms of allergy-related disease outcomes, and to investigate how worms protect against allergy-related diseases. In 2017, based on new evidence that worms may protect against metabolic diseases such as diabetes the study was extended to study the effect of the intervention against worms on insulin resistance and type 2 diabetes.

Who can participate?
The inhabitants of fishing villages in the islands of Koome sub-county, Mukono District, Uganda

What does the study involve?
Participating villages are randomly allocated to receive either the standard intervention against worms (mass treatment for schistosomiasis, with praziquantel, once a year, and for other worms, with albendazole, twice a year), or treatment with both drugs four times a year.

What are the possible benefits and risks of participating?
Participating villages are expected to benefit from regular treatment for worm infections. The treatments do have some side effects (for example praziquantel, which causes itching, rashes, dizziness and diarrhoea, especially in people with heavy worm infections) but the team provides treatment for these side effects.

Where is the study run from?
The Uganda Virus Research Institute with collaboration between the Vector Control Division of the Ugandan Ministry of Health, the UK Medical Research Council Unit at the Uganda Virus Research Institute and the London School of Hygiene & Tropical Medicine.

When is the study starting and how long is it expected to run for?
September 2012 to December 2017

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Prof. Alison Elliott
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Contact information

Type(s)
Scientific

Contact name
Prof Alison Elliott

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-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Lake Victoria Island Intervention Study on Worms and Allergy-related diseases

Acronym
LaVIISWA

Study objectives
The hygiene hypothesis proposes that exposure to infection protects against inflammatory conditions such as allergy and autoimmunity. It has been intensively studied in affluent countries

but not in low-income settings. In Africa, where infections are still the predominant threat to human health and inflammatory diseases are just beginning to emerge, there is an immediate need to determine whether effective control of infectious pathogens will result in an epidemic of inflammatory diseases that the continent is ill-equipped to address. There is also a rich opportunity to investigate immunological and genetic interactions between pathogens and inflammatory diseases in the context of exposures that the immune system evolved to combat, and to make discoveries that can be harnessed for therapeutic interventions and global health benefits.

This project is therefore designed to address the hypothesis that chronic helminth infection protects against asthma, eczema and atopy, and that effective anthelminthic treatment programmes will result in increased rates of allergy in low income countries.

Added 21/06/2017:
Inflammation has been identified as an important factor in the cause and progression of insulin resistance and type 2 diabetes. Due to their immunomodulatory properties, helminths may protect against insulin resistance and type 2 diabetes. Studies in experimental animals (mice) and cross-sectional studies in human support this hypothesis.

The extended study, therefore, will now also address the hypothesis that chronic helminth infection protects against insulin resistance and type 2 diabetes and that effective anthelminthic treatment results in increased rates of insulin resistance and type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Uganda Virus Research Institute, 02/05/2012, ref: GC/127/12/05/03
2. Uganda National Council for Science and Technology, 23/05/2012, ref: HS1183
3. London School of Hygiene & Tropical Medicine, 28/05/2012, ref: 6187

Study design
Cluster-randomised intervention trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Worm infections and their effects on general health, allergy-related conditions and metabolic parameters

Interventions
Standard intervention against helminths (as recommended by the Vector Control Division at the Ministry of Health) comprises single-dose albendazole (400 mg) given twice-yearly to all community members aged one year or above, and annual praziquantel treatment (at a dose of approximately 40 mg/kg, but estimated by a height pole) to all individuals whose height falls within the range on the height pole. This height range excludes pre-school children. This standard intervention will be compared with an intensive intervention comprising home-delivered, quarterly albendazole and praziquantel to all household members in the whole community, including preschool children.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Original primary outcome measures (assessed in a survey after three years of anthelminthic intervention):
1. Wheeze
2. Atopy (assessed by allergen-specific serum IgE)
3. Atopy (assessed by skin prick test responses)

Added 21/06/2017:
Additional primary outcome measure(s) (assessed in a survey after four years of anthelminthic intervention):
1. Insulin resistance, measured using the homeostatic model assessment of Insulin resistance [HOMA-IR]. HOMA-IR = fasting serum insulin x fasting glucose / 22.5

Secondary outcome measures
Original secondary outcome measures (assessed in a survey after three years of anthelminthic intervention):
1. Eczema (visible flexural dermatitis)
2. Helminth infection prevalence
3. Haemoglobin
4. Height and weight z-scores
5. Hepatosplenomegaly
6. Vaccine responses
7. Cognitive function in children

Additional secondary outcome measures (assessed in a survey after four years of anthelminthic intervention):
1. Fasting blood glucose; plasma glucose levels measured using the enzymatic method after an overnight fast (8 hours)
2. Glycated haemoglobin, measured using the turbidimetric inhibition immunoassay (TINIA) for hemolyzed whole blood
3. Serum lipid levels (total serum cholesterol, triglyceride levels, high density lipoprotein (HDL) - cholesterol and low density lipoprotein (LDL) - cholesterol), measured using the enzymatic

colorimetric method after an overnight fast (8 hours)
4. Blood pressure; the average of three blood pressure readings taken 5 minutes apart measured using a digital sphygmomanometer
5. Body mass index; body weight in kilograms measured using a weighing scale, divided by the square of height in metres measured using a stadiometer
5. Waist circumference; circumference at the mid-way position between the lowest rib and the iliac crest, recorded to the nearest 0.1 cm and measured using a non-stretchable measuring tape
6. Hip circumference; circumference at the level of the greater trochanters recorded to the nearest 0.1 cm and measured using a non-stretchable measuring tape
7. Markers of inflammation; pro- and anti-inflammatory cytokines measured using a customised immunoassay

Overall study start date
10/09/2012

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Fishing camp villages in Koome sub-county, Mukono District, Uganda, will be eligible for inclusion. All households in participating villages will be eligible for inclusion in the surveys. In selected and participating households, all household members, of all ages, will be eligible for inclusion in the survey.

Participant type(s)
All

Age group
All

Sex
Both

Target number of participants
The study will have two main surveys, a baseline survey and an outcome survey. At each main survey the aim is to recruit a total of 3250 people from approximately 910 households. A third survey will be conducted after four years of the anthelminthic intervention to investigate metabolic outcomes. In this survey, the aim is to recruit 1950 people.

Total final enrolment
3350

Key exclusion criteria
1. Villages will be excluded if their Local Council leaders refuse permission for them to participate
2. Households where all members refuse to participate, or where all members are absent during the survey period
3. Does not meet inclusion criteria

Date of first enrolment
01/10/2012

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Uganda

Study participating centre
Medical Research Council/UVRI Uganda Research Unit on AIDS
Entebbe
Uganda
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine (UK)

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Sponsor type
University/education

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ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type

Research organisation

Funder Name
Wellcome Trust (UK) ref: 095778

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The main trial results are expected to be published in 2017.

Intention to publish date

Individual participant data (IPD) sharing plan
Fully anonymised participant- and cluster-level data will be made available from Emily Webb (emily.webb@lshtm.ac.uk) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/04/2015		Yes	No
Results article	baseline survey results	01/08/2016		Yes	No
Statistical Analysis Plan		26/10/2016	26/10/2016	No	No
Results article	results	02/05/2019	24/07/2020	Yes	No