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Helminth infection and type 2 diabetes mellitus in Indonesia

Submission date
24/09/2013

Recruitment status
No longer recruiting

Registration date
12/11/2013

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol
Background and study aims
Helminth infections induce strong immune responses that decrease inflammation, allowing their long-term survival in the human body. These infections may decrease chronic inflammation and associated diseases, including type 2 diabetes. Asia is the major site of a rapidly emerging epidemic of diabetes. In addition to the disappearance of traditional diets, adaptation to urban conditions and related disturbances in energy balance, we propose that decreasing helminth infections in rural and urban areas may be contributing to the increase in type 2 diabetes. We want to look at the effect of drug treatment of soil-transmitted helminth infections on insulin resistance and metabolic/immunologic related factors.

Who can participate?
Men and women over 16 years of age living in the Nangapanda area, Flores Island, Indonesia can participate in the study.

What does the study involve?
Participating households are randomly allocated to receive albendazole or placebo (dummy) to be taken orally for 3 consecutive days, every 3 months for one year.

What are the possible benefits and risks of participating?
Participating households are expected to benefit from free diagnosis and treatment of soil-transmitted helminths. The treatment can have some side effects which include nausea, vomiting and other digestive symptoms, but the study team will provide treatment for these side effects.

Where is the study run from?
The study is conducted in the households of the Nangapanda area, Flores Island, Indonesia.

When is the study starting and how long is it expected to run for?
The study will start in April 2014 and is expected to run for a year and a half.

Who is funding the study?
Royal Netherlands Academy of Arts and Sciences (KNAW).

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
57-SPIN3-JRP

Study information

Scientific Title
Helminth infection and type 2 diabetes mellitus in Indonesia: integrating parasitological, immunological, behavioral and metabolic studies

Study objectives
Soil-transmitted helminth infections suppress insulin resistance and this suppression is reversible by antihelminthic treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Ethics Committee, Faculty of Medicine, Universitas Indonesia Cipto Mangun Kusumo Hospital, Jakarta, Indonesia, 09/09/2013, reference number:549/H2.F1/ETIK/2013

Study design
Household-based 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
Soil-transmitted helminth infection

Interventions
Households are randomized to two groups:
1. 400 mg albendazole
2. Placebo
Given orally for 3 consecutive days, every 3 months. Patients are followed up for one year.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Changes in insulin resistance as assessed by HOMA-IR (Homeostatic Model of Assessment-Insulin Resistance), one year post treatment

Secondary outcome measures
Energy metabolism and immunological parameters related to energy metabolism, measured one year post treatment.
1. Changes in body mass index and waist circumference measured by SECA tools
2. Changes in serum fasting blood glucose and HBA1c using a glucose meter
3. Changes in serum lipid levels, measured by commercial enzymatic kits
4. Changes in helminth load, measured by polymerase chain reaction (PCR)
5. Changes in immune polarization: FACS, intracellular staining, enzyme-linked immunosorbent assay (ELISA)

Overall study start date
01/04/2014

Completion date
01/10/2015

Eligibility

Key inclusion criteria
1. Those who have given informed consent
2. Both males and females
3. Aged 16 years or older
4. Live in Nangapanda area, Flores Island
5. Good health, without any serious clinical condition

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1580

Key exclusion criteria
1. Subjects younger than 16 years
2. Active treatment for diabetes mellitus
3. Serious concomitant disease
4. Pregnant women
5. No informed consent

Date of first enrolment
01/04/2014

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
Indonesia

Netherlands

Study participating centre
Radboud University Nijmegen Medical Center
Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
The Royal Netherlands Academy of Arts and Sciences (Netherlands)

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Kloveniersburgwal 29
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Sponsor type
Research organisation

ROR
https://ror.org/043c0p156

Funder(s)

Funder type
Research organisation

Funder Name
Koninklijke Nederlandse Akademie van Wetenschappen

Alternative Name(s)
Royal Netherlands Academy of Arts and Sciences, KNAW

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

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?

Protocol article	protocol	18/03/2015		Yes	No
Results article	results	17/11/2018	22/01/2019	Yes	No
Results article	results	18/03/2015	22/01/2019	Yes	No
Results article	results of the effect of anthelmintic treatment on insulin resistance.	01/09/2017	22/01/2019	Yes	No
Results article	results of the effect of anthelmintic treatment on leptin, adiponectin and leptin to adiponectin ratio.	16/10/2017	22/01/2019	Yes	No