Helminth infection and type 2 diabetes mellitus in Indonesia

Submission date	Recruitment status		
24/09/2013	No longer recruiting		
Registration date 12/11/2013	Overall study status Completed		
Last Edited	Condition category		
22/01/2019	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 soiltransmitted 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? Professor Johannes W.A. Smit, MD PhD J.Smit@aig.umcn.nl

Contact information

Type(s)

Scientific

Contact name Prof Johannes W.A. Smit

Contact details

Dept.of General Internal Medicine Radboud University Nijmegen Medical Center P.O. Box 9101 Nijmegen Netherlands 6500 HB

J.Smit@aig.umcn.nl

Type(s)

Scientific

Contact name Prof Maria Yazdanbakhsh

Contact details

Dept. of Parasitology Leiden University Medical Center Postbus 9600 Leiden Netherlands 2300RC +31 (0)715 265 067 m.yazdanbakhsh@lumc.nl

Type(s)

Scientific

Contact name Dr Taniawati Supali

Contact details

Dept. of Parasitology Faculty of Medicine University of Indonesia Salemba Raya 6 Jakarta Indonesia 10430 +62 (0)213 914 607 taniawati@yahoo.com

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)

Sponsor details Kloveniersburgwal 29 Amsterdam Netherlands 1011 JV knaw@knaw.nl

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 Details type

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