







Helminth infection and type 2 diabetes mellitus in Indonesia

Submission date 24/09/2013	Recruitment status No longer recruiting	 Prospectively registered
		 Protocol added
Registration date 12/11/2013	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 22/01/2019	Condition category Infections and Infestations	 Raw data not yet added
		 Study completed

Plain English Summary

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?
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

Protocol/serial number

57-SPIN3-JRP

Study information

Scientific Title

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

Study hypothesis

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

Condition

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

Overall study end date

01/10/2015

Eligibility**Participant 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

Participant 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

Recruitment start date

01/04/2014

Recruitment end date

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 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