500FG-DM project

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To characterize the interaction between the genetic background, the microbiome, and the immune responses in patients with diabetes type 1, both cross-sectional and over time, and to identify the disturbances in this interaction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42705

Source
ToetsingOnline

Brief title
500FG-DM

Condition

- Other condition
- Immunodeficiency syndromes
- Hepatobiliary neoplasms malignant and unspecified

Synonym
diabetes type 1, high blood sugar

Health condition

autoimmuunziekten

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: STW project Biomarker Development Center

Intervention

Keyword: Immunology, Metabolomics, Microbiome, Transcriptomics

Outcome measures

Primary outcome

Metadata: Lifestyle questionnaires

DNA: Gene polymorphisms at DNA level

Microbiome: Presence of groups of bacteria

Phenotype: Specific populations of cells

Functional data: Cytokine production

Secondary outcome

nvt

Study description

Background summary

Rationale: The response of the host to exogenous (e.g. infectious) or endogenous (e.g. metabolic) stressors depends on the genetic make-up of the host on the one hand, and environmental factors on the other hand. One of the most important environmental components that influences human physiological responses is the colonizing microbial flora. In a healthy human body, more microbial cells are present on the skin and mucosae (e.g. oral, gut, vagina) than normal human cells. Due to the important effects of the colonizing microflora for multiple biological processes (e.g. host defense, digestion, etc), a finely tuned balance between the microorganisms that form the microbiome and the host is very important for the maintenance of health. This balance might be disturbed in people suffering from chronic inflammatory diseases, infections or metabolic diseases.
It has been recently hypothesized that these two factors, genetic and

environmental (in this case the microbiome), strongly influence each other and the immune system of the host. Furthermore, it has been demonstrated that microbiome composition can change over time and seasonal changes have been reported. In this respect, the interaction between the genome, the microbiome and the immune response becomes crucial for the health status of an individual and for the development of disease. Therefore, a comprehensive analysis of the genome-microbiome-host defense interaction is currently performed in 500 healthy individuals (500FG project, 2012-550, NL42561.091.12). However, it is not known how this interaction is affected in patients with infections or inflammatory diseases.

Study objective

To characterize the interaction between the genetic background, the microbiome, and the immune responses in patients with diabetes type 1, both cross-sectional and over time, and to identify the disturbances in this interaction.

Study design

The explorative study will be performed in the RadboudUMC The duration of the study is 3 years. This explorative study starts with recruiting patients at the RadboudUMC.

Study burden and risks

Burden:
- For patients: collection of venous blood, if possible during regular blood sampling. This comprises a maximum of 1 PaxGene tube a 8 mL, and 6 EDTA tubes à 10 ml and 1 serum tube à 5 ml.

Risks:
- No risks other than local hematoma are related to venous puncture.

Benefit:
There will be no benefits for the subjects enrolled in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age > 18 years
diagnosis type 1 diabetes based on clinical criteria with or without anti-GAD positivity

Exclusion criteria

Pregnancy or breastfeeding during inclusion period
Age<18 years

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2016
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-11-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL54214.091.15