Impact of microbial communities on obesity

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The aim of this study is to test the hypothesis that obesity and the microbial community in the human GI tract are linked

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metabolism disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31153

Source
ToetsingOnline

Brief title
Impact of microbial communities on obesity

Condition

- Metabolism disorders NEC

Synonym
corpulence, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: GI tract Microbiota, monozygotic twins, obesity, phenotype

Outcome measures

Primary outcome

From 40 monozygotic twin pairs the bacterial composition of their fecal microbiota, their weigth, length and BMI will be determined. Within each pair comparisons between the microbiotas will be made at different taxonomic levels. These pair-wise comparisons will determine if significant differences exists between pairs with different bmi compared to those having a similar bmi.

Secondary outcome

Not applicable: 0

Study description

Background summary

Several studies have indicated that the host-genotype related factors have an important role on the microbial community in the GI tract. In addition, energy efficiency and balance of humans have also clear genetic links. Energy harvest starts with digestion of dietary components in the GI tract in which microbes play an important role. This motivated us to form the hypothesis that energy efficiency and thus obesity might be linked to the microbial community in the GI tract.

Study objective

The aim of this study is to test the hypothesis that obesity and the microbial community in the human GI tract are linked

Study design

This observational study focuses on studying the diversity of microbial communities in the GI tract of various monozygotic twins in detail and determine the relation between community structure and the obese phenotype

Study burden and risks

Length, weight and BMI will be measured and fecal samples will be collected from the volunteers. There are no risks concerning these procedures. In addition, filling in a questionnaire concerning the personal (gender, age, etc) and health information of the volunteers will be asked

Contacts

Public
Wageningen Universiteit

Hesselink van Suchtelenweg 4
6703 CT Wageningen
Nederland
Scientific
Wageningen Universiteit

Hesselink van Suchtelenweg 4
6703 CT Wageningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Subjects must be able to understand the written study information and must be able to sign an informed consent
-Twin living separately for more than 5 years
-twin pairs who will differ more than 5 kg/m2 in Body Mass Index (BMI)
-Twin pairs who will have a similar BMI
-Where possible a sibling, not older/younger than 5 years than the twin, will be included

Exclusion criteria

Recent history (i.e. last month) or current use of medication that may affect the intestinal microbiota.
-Use of pre- and/or probiotics (for at least one month before collection of the fecal samples).
-Pre-exiting bowel diseases
-Pregnancy/breast feeding

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-11-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2007
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL18323.081.07