Measurement of gut permeability in healthy people with a different metabolic profile.

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20611

Source
Nationaal Trial Register

Health condition

Metabolic health (waist circumference, BMI, fasting glucose, HbA1c, LDL cholesterol, HDL cholesterol, total cholesterol, total triglycerides, ALT, GGT and hsCRP)

Sponsors and support

Primary sponsor: Stichting Dienst Landbouwkundig Onderzoek
Wageningen UR Food & Biobased Research
Consumer Science & Health
Bornse Weilanden 9
6708 WG Wageningen
Source(s) of monetary or material Support: Suntory Global Innovation Center Limited, Japan

Intervention

Outcome measures

Primary outcome

The main study parameter is gut permeability assessed by a MS permeability test. In this test, gut permeability is reflected by the urinary excretion levels of sucrose, lactulose, rhamnose, sucralose and erythritol. These sugars are measured in 3 urine fractions that are collected during 24 hours after consumption of a MS mix solution containing these five sugars. Gut permeability will be compared between metabolic healthier and metabolic unhealthier subjects.

Secondary outcome

Secondary parameters are fasting state levels of leaky gut biomarkers (LPS, LBP, sCD14, zonulin and leptin) and metabolic health parameters (waist, BMI, HbA1c, glucose, LDL cholesterol, HDL cholesterol, total cholesterol, total triglycerides, ALT, GGT and CRP). These parameters will be compared between metabolic healthier and metabolic unhealthier subjects and correlated with gut permeability as assessed by the MS permeability test.

Study description

Background summary

There is growing evidence that gut permeability (or a ‘leaky gut’) can be linked to metabolic health and might therefore be involved in development of metabolic disorders related to the metabolic syndrome. In the Permeable study, we want to expand our knowledge on if and how the intestinal barrier relates to metabolic health. This knowledge could be fundamental to further identify and explore compounds that can strengthen the intestinal barrier and thereby contribute to metabolic health and the prevention of metabolic disorders.

The objective of the study is to compare gut permeability in metabolic healthier and metabolic unhealthier subjects by performing a multi-sugar (MS) permeability test and determine the correlation between gut permeability and metabolic health status.

The Permeable study is an observational study, in which gut permeability is assessed by a MS permeability test, with and without an acetylsalicylic acid challenge. On the day of the MS test, first a fasting blood sample is collected. Subsequently, subjects consume 200 ml MS mix solution (containing sucrose, lactulose, rhamnose, sucralose and erythritol) and urine is collected in three fractions (0-2 hours, 2-5 hours and 5-24 hours). During the second visit, the same procedures are repeated, except the subjects will consume acetylsalicylic acid before the MS test (1000mg in the evening and 1000mg in morning prior to the test).

The study will be performed with apparently healthy adult volunteers, age between 20-70 years old. Based on waist circumference, fasting glucose and HDL cholesterol, two groups (n=15 per group) differing in metabolic health (metabolic healthier and metabolic unhealthier) will be selected to participate in the study.

Study objective

There is growing evidence that gut permeability (or a 'leaky gut') can be linked to metabolic health and might therefore be involved in development of metabolic disorders related to the metabolic syndrome. We hypothesize that gut permeability is related to metabolic health.

Study design

The gut permeability test will be assessed twice, once without and once with an aspirin challenge prior to the test.

Intervention

No intervention

Contacts

Public
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Eligibility criteria

Inclusion criteria

-Apparently healthy

-Age range between 20-70 years old (the two groups should be age balanced as much as possible)

-Men and women (the two groups should be gender balanced as much as possible)

-Highest and lowest values for 1) waist circumference, 2) fasting glucose, 3) (HDL-) cholesterol

Exclusion criteria

-Gastrointestinal disorders (stomach ulcer, ulcerative colitis, Crohn¡¯s disease, celiac disease)

-History of gastrointestinal surgery

-History of liver dysfunction (cirrhosis, hepatitis)

-Diabetes mellitus

-History of heart attack

-Heart failure

-Kidney dysfunction

-Intake of medications known to change the inflammatory status (i.e proton pump inhibitors, antibiotic, anti-inflammatory medication (including NSAIDs)

-Hypersensitivity to NSAIDs or the sugars in the multi-sugar mix solution

-Pregnancy

-Age below 20 or over 70 years

-Alcohol intake ¡Ý 3-4 glasses of beer/wine per day

-Drug abuse

-Current smokers

-Participation in other clinical trials in the past month

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-07-2016
Enrollment:	30
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43291
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4059
NTR-old	NTR5943
CCMO	NL57555.081.16
OMON	NL-OMON43291

Study results