Is metabolic health in humans related to gut permeability?

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

Summary

ID

NL-OMON43291

Source
ToetsingOnline

Brief title
Metabolic health and gut permeability

Condition

- Other condition
- Gastrointestinal conditions NEC

Synonym
gut permeability, 'leaky gut'

Health condition

metabole gezondheid, (voorstadia) metabool syndroom

Research involving
Human

Sponsors and support

Primary sponsor: Suntory Global Innovation Center Limited
Source(s) of monetary or material Support: Suntory Global Innovation Center Limited;Japan (zie ook sectie J. Aanvullende opmerkingen)

Intervention

Keyword: gut permeability, intestine, metabolic health, multi-sugar test

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. Recently, a multi-sugar (MS) permeability test was developed to more accurately assess gut permeability compared to the classical dual sugar tests. Next to this MS permeability test, also other potential leaky gut-related markers in blood (LPS, LBP (LPS-binding protein), sCD14 (soluble CD14), leptin and zonulin) that are related to metabolic health could provide additional information on gut permeability. 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.

Study objective

The primary objective of the study is to compare gut permeability in metabolic healthier and metabolic unhealthier subjects by performing a MS permeability test. The secondary objectives are to study the correlation between gut permeability assessed by a MS permeability test and 1) metabolic health status and 2) previously identified potential leaky gut markers LPS, LBP, sCD14, leptin and zonulin.

Study design

The Permeable study is an observational study, in which gut permeability is assessed by a MS permeability test. The MS test will be performed with and without an acetylsalicylic acid challenge and therefore each subject will visit the research facility twice. On the day of the MS test, first weight and height are measured and 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). Five hours after drinking the MS mix, subjects receive a standardized lunch and then urine collection continues till the next morning at home, where they are allowed to eat normally (with restriction of lactulose, rhamnose, sucralose and erythritol, alcohol, caffeine (including tea) and spicy foods). During the second visit, at least 4 days later, 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).

Study burden and risks

The burden for participants in this study is relatively low. They only have to

visit the research facilities twice. However, participants might experience some level of burden from fasting overnight and fasting during the first 5 hours of the MS permeability test. Also the temporary deprivation of caffeine and alcohol might elicit an unpleasant feeling for some of the participants. The risks for participation are very small. A fingerstick measurement (once) and drawing blood (twice) can be a little painful and in exceptional cases, a bruise may occur. The amount of blood that is drawn from participants is minimal (10-12ml) and it is not expected that this gives rise to problems for adults. Only very occasionally, a hypo- or hyperglycaemic response may occur after drinking the MS mix solution and some people might experience gastrointestinal complaints after intake of acetylsalicylic acid .
There are no direct benefits for the participants, except for the fact that they receive information about their metabolic health profile.

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

- Apparently healthy (not meeting any of the exclusion criteria)
- Age range between 20-70 years old
- Men and women
- Highest and lowest values for 1) waist circumference, 2) fasting glucose, 3) (HDL-) cholesterol; assessed during screening procedure.

Exclusion criteria

- Gastrointestinal disorders (stomach ulcer, ulcerative colitis, Crohn*s disease, celiac disease)
- History of gastrointestinal surgery
- Liver dysfunction (cirrhosis, hepatitis)
- Diabetes mellitus
- History of acute coronary syndrome
- Heart failure
- Kidney dysfunction (eGFR<60ml/min)
- Thromboembolic disorders
- 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 MS mix
- Pregnancy (will not be tested within the Permeable study)
- Age below 20 or over 70 years
- Alcohol intake * 40g/day (* 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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2016
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

ID: 20611
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL57555.081.16
Other	Permeable studie is wel al aangemeld (op 25-4-2016) bij Nederlands Trial Register (www.trialregister.nl) en identificatienummer wordt binnen 4 weken na aanmelding toegekend.
OMON	NL-OMON20611