Methods to examine intestinal permeability under different conditions.

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The effect of a high-fat breakfast on intestinal permeability will be examined in lean and obese men to see if a fat load can induce increased intestinal permeability and it is a feasible challenge test to investigate effects of foods / ingredients...

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

Summary

ID

NL-OMON32575

Source
ToetsingOnline

Brief title
Intestinal permeability.

Condition

- Other condition
- Malabsorption conditions

Synonym
intestinal permeability, irretable bowel syndrome

Health condition

darmdoorlaatbaarheid wordt gemeten in gezonde mannen

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Volksgezondheid, Welzijn en Sport (VWS)
Source(s) of monetary or material Support: Ministerie van OC&W,ministerie van VWS

Intervention

Keyword: fat load, health, intestinal permeability, sugar absorption test

Outcome measures

Primary outcome

Intestinal permeability will be examined with an absorption test using four different sugars (sucrose, mannitol, sucralose and lactulose). New markers of intestinal permeability, like I-FABP, L-FABP, LPS and inflammatory markers will be measured as well.

Secondary outcome

Trait Anxiety inventory (baseline stress level as a character trait).

Body resistance in relation with intestinal permeability.

Study description

Background summary

Intestinal permeability of subjects can vary depending on their health status. It is therefore important to be able to measure and quantify intestinal permeability in a standardized way. Subjects with intestinal complaints (like irritable bowel disorder) or obese subjects have been found to have increased intestinal permeability. Different physiological conditions might affect intestinal permeability (IP) further.
In the clinic, sugar absorption tests and different blood and urine markers have been used to quantify IP. The sugars sucrose, mannitol, sucralose and lactulose are absorbed differently in the small or large intestines, resulting in different sugar levels in urine. This indicates the level of intestinal permeability and the location of increased permeability which is more or less permeable.
A high-fat meal could be used as a challenge test to increase IP in subjects

even further. After a high fat meal, lipopolysaccaride (LPS) could be co-transported with chylomicrons. Small amounts of LPS co-transit with dietary fat from the gut after a high-fat meal, which thereby increases plasma LPS concentrations.
Because of the above mentioned reasons, it could be relevant to determine intestinal permeability and plasma LPS concentration after consumption of a high-fat diet.
Different methods will be used to determine the intestinal permeability in lean and obese men, under different conditions. New parameters, like intestinal (I) fatty acid binding protein (I-FABP), liver (L)-FABP, LPS and inflammatory markers will be measured and related to outcomes of tests, to examine the relation with intestinal permeability.
The association of IP with whole body electrical resistance will be examined, to determine usefulness of a candidate non-invasive method for IP investigation.

Study objective

The effect of a high-fat breakfast on intestinal permeability will be examined in lean and obese men to see if a fat load can induce increased intestinal permeability and it is a feasible challenge test to investigate effects of foods / ingredients on intestinal permeability. Methods and candidate biomarkers to investigate intestinal permeability are the main focus of the study.

Study design

The study is designed as a randomized, cross-over and open study.

Intervention

On two different test days eight lean and eight obese men will be supplied with a sugar drink to examine intestinal permeability under normal conditions and in combination with an oral fat load to examine intestinal permeability under stressed conditions.

Study burden and risks

Healthy lean and obese men will participate in a study to examine the difference in acute intestinal permeability due to body weight differences. Lean and obese subjects might represent a range in physiological homeostasis, with the obese being representatives with a physiological condition in whom less flexibility to challenges are expected. On one of the test days subjects will be given an oral fat load as a nutritional challenge test. The effect of this challenge on the intestinal permeability is determined. Subjects will visit TNO twice for a test day of seven hours and twice for return of collected

urine. Blood samples will be drawn frequently (nine times on a test day). Urine will be collected for 24 hours. No risk or real burden is of concern in this study.

Contacts

Public
Ministerie van Volksgezondheid, Welzijn en Sport (VWS)

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Healthy as assessed by the
- health and lifestyle questionnaire (P8738 F02; in Dutch)
- results of the pre-study laboratory tests
2. Males aged >= 18 and <= 45 years at Day 01 of the study
3. Body Mass Index (BMI): for the lean : >= 20 and <= 25 kg/m2; obese >= 30 and <= 35 kg/m2
4. Normal Dutch eating habits as assessed by P8738 F02

5. Voluntary participation
6. Having given written informed consent
7. Willing to comply with the study procedures
8. Appropriate veins for blood sampling/canulla insertion according to TNO
9. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
10. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

Exclusion criteria

1. Participation in any clinical trial including blood sampling and/or administration of substances up to 30-90 days before Day 01 of this study
2. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, inhalator administration of substances
3. Having a history of medical or surgical events that may significantly affect the study outcome, including cardiovascular disease or hypertension, stomach and intestinal complaints (and medication), pre-diabetes and Diabetes Mellitus
4. Having stomach and/or intestinal complaints after consumption of a high-fat meal
5. Usage of NSAIDs and/or acetylsalicyl acid (for example ibuprofen, diclofenac, naproxen or aspirin)
6. Smoking
7. Alcohol consumption (> 28 units/week)
8. Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening
9. Reported slimming or medically prescribed diet
10. Recent blood donation (<1 month prior to the start of the study)
11. Not willing to give up blood donation during the study.
12. Personnel of TNO Quality of Life, their partner and their first and second degree relatives
13. Not having a general practitioner
14. Not willing to accept information transfer, concerning participation in the study, or information regarding his health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2010
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	12-01-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL30957.028.09