Gut microbiotica composition and postprandial effect on endotoxemia in obese healthy males and obese insulin resistant males

Published: 17-02-2014
Last updated: 24-04-2024

The aim for this study is to investigate feces composition and postprandial effect, as done with oral fat loading test (OFLT), on endotoxemia (e.g. LPS and Ralstonia levels) in plasma as assessed with qPCR.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON40534

Source
ToetsingOnline

Brief title
PEP study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
postprandial endotoxemia, postprandiale bacterielevels

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endotoxemia, gutmicrobiota, postprandial

Outcome measures

Primary outcome

The fecal gutmicrobiota composition and the postprandial endotoxemia (e.g. LPS

and Ralstonia) in obese healthy males and obese insulin resistant males.

Secondary outcome

N/A

Study description

Background summary

There is a worldwide epidemic of obesity, which is a major risk factor for the development of common medical conditions such as type 2 diabetes, dyslipidemia and subsequent cardiovascular disease. Novel insights show that gut microbiota composition altered by diet takes a great part in the development of postprandial endotoxemia, which is thought to be related to the inflammatory process in the adipose tissue. These inflammatory changes, such as the level of influx of CD68+ macrophages into adipose visceral, can trigger a local and systemic inflammatory response with disturbed adipocyte lipolysis, which in turn induces insulin resistance in other tissues such as liver and muscle. Therefore we aim to investigate the feces composition and the postprandial effect on endotoxemia (e.g. LPS and Ralstonia) in plasma in lean healthy males and obese insulin resistant males

Study objective

The aim for this study is to investigate feces composition and postprandial effect, as done with oral fat loading test (OFLT), on endotoxemia (e.g. LPS and Ralstonia levels) in plasma as assessed with qPCR.

Study design

This is an observational study with an OFLT.

Study burden and risks

Subjects will visit the hospital twice. During the first visit, informed consent will be signed and patients are screened for eligibility. When subjects can be included in the study they are asked to visit the AMC for the second time. There the collection of the patients* morning stool will be handled. Hereafter the oral fat loading test will take place to asses postprandial endotoxemia (e.g. LPS and ralstonia) in plasma. This study does not have specific advantages for the subjects. The results of this observational study may help us to understand the role of gutmicrobiota in the feces in the development of postprandial endotoxemia. Total study duration for each subject will be about 10 hours. Fat loading test is a routine test in our department which requires repetitive blood sampling from an indwelling venous catheter after the consumption of cream and Vitamin A. This test does not cause any side effects. We believe the information gathered from this study outweighs the burden of this investigation.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9 9
Amsterdam ZO 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9 9
Amsterdam ZO 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy male subjects (N<=10) at least 18 years of age
BMI above 25 kg/m2
subjects should be able and willing to give informed consent

Exclusion criteria

Smoking
Medication use
Cardiovasculair disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-02-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL46705.018.13