Effect of fat consumption of VOC profile in breath

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The main objective of the present study is to investigate whether it is possible to use the VOC pattern in exhaled air as a parameter of metabolism of lipids. Primary Objective: To investigate the difference in postprandial change in volatile organic...

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Other condition **Study type** Interventional

Summary

ID

NL-OMON46889

Source

ToetsingOnline

Brief title

Breath Taking!

Condition

Other condition

Synonym

Lipid metabolism

Health condition

metabolisme van vetten

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: FrieslandCampina Nederland B.V

Intervention

Keyword: breath, fat, VOC

Outcome measures

Primary outcome

The main study objective is the postprandial change in VOCs from exhaled air.

This parameter will be studied to gain insight in the the intra-subject

variation of VOC profile in exhaled air in a fasted state and after consumption

of a low- or high-fat drink.

Secondary outcome

The secondary study objectives are parameters (which will be investigated

during part II of the study) to investigate whether specific VOCs in exhaled

air after fat consumption can be linked to postprandial VOCs in blood; and to

investigate whether specific VOCs in exhaled air after fat consumption can be

linked to postprandial (metabolic) parameters.

Therefore, the secondary parameters are:

* Postprandial change in VOCs from blood samples

* Blood levels: as indication of fat absorption and metabolism

o Plasma lipid profile over 5 hours after consumption of milk drinks (level of

free fatty acids (FFA), level of LDL, HDL and VLDL, total cholesterol,

triglycerides and cholesterol in chylomicron-rich fractions and size of those

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fractions)

- o Apolipoprotein B48
- o Apolipoprotein A-IV
- o Glycated haemoglobin (only at baseline)
- o Etc.
- * Respiratory exchange ratio (RER) (ratio of CO2 production and O2

consumption). The CO2 produced and O2 consumed by participants will be measured

in resting condition, pre- and 5 hours postprandial with the usage of a

ventilated hood system (Max II Metabolic Cart, AEI technologies).

Study description

Background summary

Currently, the effects of nutrition or specific food components, including those on absorption or metabolism, are mostly studied via parameters in blood samples. To reduce the burden for participants of nutritional intervention studies, there is a high need for non-invasive methods. Exhaled air contains large numbers of volatile organic compounds (VOCs) that may be derived from the body*s internal metabolism. So this seems to be an interesting, non-invasive parameter.

Study objective

The main objective of the present study is to investigate whether it is possible to use the VOC pattern in exhaled air as a parameter of metabolism of lipids.

Primary Objective:

To investigate the difference in postprandial change in volatile organic compounds (VOCs) pattern from exhaled air, between a dairy drink with 0.1% fat and a dairy drink with 10% fat, and investigate whether this is related to parameters of lipid metabolism.

Secondary Objectives:

* To study the intra-subject variation of VOC profile in exhaled air in a

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fasted state and after consumption of a high-fat drink

- * To study differences between online and offline measurements of VOC pattern in exhaled air
- * To identify VOCs that are linked to consumption of a dairy drink
- * To investigate whether a VOC pattern in exhaled air after fat consumption can be linked to postprandial VOC pattern in blood
- * To investigate whether a VOC pattern in exhaled air after fat consumption can be linked to postprandial (metabolic) parameters.

Study design

This study will be a randomized cross-over study. This study will not be blinded, because the taste and mouthfeel of the two drinks is very different and will be easily recognized by the participants. The study will consist of 13 study days.

Intervention

The subjects of this study will receive, at study days 1-4 and 10, a high-fat drink, which will be a dairy drink consisting of full cow*s milk, cream, skim milk powder and lactose (total of 10% fat). At study days 5-10 and 12-13 participants will receive either this high-fat drink or a low-fat version of this drink. The low-fat drink will be skimmed cow*s milk (0.1% fat). A total of 500 ml of the milk drink will be consumed.

Study burden and risks

A cannula will be installed to take blood samples. This might cause some bruising and sore muscles.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- * Caucasian male
- * 18-35 years old
- * Body mass index (BMI) 22-25 kg/m2.
- * Fat percentage between 8 * 15%
- * Regular consumption of milk (products)

Exclusion criteria

- * (symptoms of) cow*s milk allergy
- * Lactose intolerance
- * Metabolic diseases
- * (known symptoms of) (auto)immune diseases, like diabetes
- * (known symptoms of) intestinal diseases, like; irritable bowel syndrome Intestinal malabsorption, diagnosed with celiac disease, Crohn*s disease, colitis ulcerosa, short bowel syndrome or surgical bowel interventions leading to malabsorption;
- * Usage of medication
- * Usage of hard drugs
- * History of smoking
- * Claustrophobia
- * Unsuitable veins for blood sampling
- * Blood donation during the two months before the start of the study
- * Current participation in other scientific studies

Study design

Design

Study type: Interventional

Intervention model: Crossover

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-05-2016

Enrollment: 12

Type: Actual

Ethics review

Approved WMO

Date: 09-05-2016

Application type: First submission

Review commission: METC Wageningen Universiteit (Wageningen)

Approved WMO

Date: 18-05-2017

Application type: Amendment

Review commission: METC Wageningen Universiteit (Wageningen)

Approved WMO

Date: 08-03-2018

Application type: Amendment

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 NL56722.081.16