Role of brown fat and skeletal muscle in post-prandial clearance of triglycerides during and after cold exposure

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1. To examine the effect of cold on post-prandial triglyceride metabolism using a standardized meal test during and after cold exposure 2. To examine the relationship between cold-induced brown adipose tissue activity and the changes in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine and glandular disorders NEC
Study type	Interventional

Summary

ID

NL-OMON47578

Source
ToetsingOnline

Brief title
The effect of cold exposure on post-prandial metabolism of triglycerides

Condition

- Endocrine and glandular disorders NEC
- Lipid metabolism disorders

Synonym
Hypertriglyceridaemia, too much lipids in the bloodstream

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brown adipose tissue, Cold exposure, Post-prandial metabolism, Triglycerides

Outcome measures

Primary outcome

Meal test: post-prandial metabolism of triglycerides, cholesterol and

lipoprotein.

PET/CT: Presence and activity of brown adipose tissue, as measured by PET/CT

scan

Muscle biopsy: cell culture, the role of skeletal muscle on the post-prandial

clearance of triglcyerides

Energy expenditure: measured by indirect calorimetry

Secondary outcome

Skin temperature: measured via iButtons on different places on the skin

Core temperature: measured via a sensor in the gastro-intestinal tract

Study description

Background summary

Cardiovascular disease forms a major health problem in the Western world. An important risk factor is hyperlipidemia, with elevated blood levels of cholesterol and triglycerides. Earlier studies have shown that in both mice (Khedoe PP et al, J Lip Res 2015) and in humans (Chondronikola M et al Cell Metab 2016) that brown adipose tissue, when activated through cold, will consume its intracellular lipid storage. The last mentioned study also showed decreased plasma levels of triglycerides after cold exposure. The idea is that brown adipose tissue, after combusting its own lipid storage, will take up plasma fatty acids, presumably to replenish its intracellular storage.

With this study we hope to show that plasma triglyceride levels can be reduced by cold exposure. We will study this by using meal tests during and after cold exposure. These results will be correlated with measurements of brown fat activity in these subjects, using a PET/CT scan.

Study objective

1. To examine the effect of cold on post-prandial triglyceride metabolism using a standardized meal test during and after cold exposure
2. To examine the relationship between cold-induced brown adipose tissue activity and the changes in triglycerides during a standardized meal test. 3. To examine the role of muscle tissue on cold-induced post-prandial triglyceride metabolism.

Study design

The test subjects will undergo three meal tests, in which they will cosnume 2 high-fat milkshakes. The first meal test will take place under thermoneutral conditions, the second meal test during cold exposure, and the third meal test after cold exposure. On a seperate day, the presence and activity of brown adipose tissue will be measured with a PET/CT scan.

Intervention

Test subjects will be exposed to cold during the second and third meal test. During this cold exposure the point of shivering is reached, to maximize the non-shvering thermogenesis and stimulate brown adipose tissue activity.

Study burden and risks

The risks in this study are small, and the possible cosnequences af a small impact.
After vena puncture or the placement of an intravenous cannula, a haematoma may occur.
After the muscle biopsy, there is a risk of infection, bleeding, haematoma or local nerve damage. Test subjects can experience a painful sensation at the site of the biopsy for a couple of days.
During the PET/CT scan and the screening incidental findings could be made.

The amount of radiation is classified as low.

Further there is a considerable amount of time investment asked of subjects, although test subjects are free to choose to participate in this study.

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

- Signed informed consent
- Caucasian
- Aged 20-50 years at the start of the study
- Body mass index (BMI) 20-30 kg/m2
- Stable dietary habits (no weight loss or gain of more than 5 kg in the past 3 months
- Stable sedentary lifestyle (not more than 2 hours of sports per week)

Exclusion criteria

- Use of cholesterol or lipid-lowering medication
- Active diseases (cardiovascular, diabetes mellitus, liver, kidney, cancer or other)

- Participation in earlier research that included PET/CT scanning for detection of brown adipose tissue activity in the last 3 months
- Alcohol consumption of >2 servings per day
- Smoking in the past 6 months
- Haemoglobine content <8.4 mmol/L

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2018
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Date:	20-09-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL61819.068.17