Polydextrose and Soluble Gluco Fiber as a dietetic aid to reduce the risk of type 2 diabetes mellitus.

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Controlling the glycemic impact of food products may reduce glycemic and insulinemic responses. This may result in a decreased inhibition of fat oxidation rate and lower plasma TAG concentration. A higher postprandial fat oxidation may result in…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON35063

Source
ToetsingOnline

Brief title
Soluble fibers and fat oxidation

Condition

- Diabetic complications
- Lipid metabolism disorders

Synonym
overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: gesponsord door industrie,Tate and Lyle

Intervention

Keyword: fat oxidation, fibers

Outcome measures

Primary outcome

The primary outcome parameter is the difference in postprandial fat oxidation

after the four different dietary treatments.

Secondary outcome

Secondary endpoints are differences in energy expenditure, substrate oxidation

of carbohydrates, plasma profile of FFA and TAG and glucose and insulin

responses

Study description

Background summary

The prevalence of obesity and insulin resistance appear to increase in the European population, and they are two important components of the metabolic syndrome. These metabolic abnormalities increase the risk of type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD).
Both genetic and environmental factors (physical activity and diet) play an important role in the etiology of these chronic metabolic diseases. Obesity develops as a result of an imbalance between energy intake and energy expenditure, resulting in a positive energy balance. Although many factors promote a positive energy balance, there is sound evidence that a western diet rich in a large amount of rapidly available carbohydrates (cooked starches) and added refined sugars (sucrose, high fructose corn syrup) may be counter-productive to body weight control and glycemic control.The latter because they markedly increase postprandial glycemia and insulinemia, thereby inhibiting adipose tissue lipolysis and/or muscle fat oxidation and, as such may promote fat storage in both adipose and non-adipose tissue. Greater postprandial fat storage in non-adipose tissue, such as skeletal muscle and liver tissue, has been associated with the development of insulin resistance, whilst postprandial hyperglycemia per se is a strong risk factor for the development of T2DM and cardiovascular comorbidities. Finally, hyperinsulinemia may actually have less favourable effects on blood lipid profile. Potential

negative side effects of high carbohydrate diets may be counteracted by the use of low glycemic index (GI) foods. The ingestion of slowly digestible carbohydrates (soluble fibers) may attenuate postprandial glycemia, reduce insulinemia, and enhance fat oxidation, all of which may assist to prevent body weight gain and insulin resistance. The use of low glycemic diets may be of relevance in dietary strategies to modulate body weight, improve insulin sensitivity and reduce cardiovascular risk.

Study objective

Controlling the glycemic impact of food products may reduce glycemic and insulinemic responses. This may result in a decreased inhibition of fat oxidation rate and lower plasma TAG concentration. A higher postprandial fat oxidation may result in less lipid accumulation in non-adipose tissues, thereby improving insulin sensitivity and the metabolic profile in the longer term. Therefore, the primary objective of the current study is to investigate the effect of a reduction in glycemic load by the use of two different soluble fibers (polydextrose and soluble gluco-fiber) on postprandial fat oxidation rate. Secondary objectives are the differences in energy expenditure, substrate oxidation of carbohydrates, plasma profile of free fatty acids (FFA) and TAG and glucose and insulin responses.

Study design

In this project we will examine the effect of soluble fibers on postprandial fat oxidation rate and plasma FFA and TAG concentration in a randomized single-blind crossover design.
First, subjects will be invited for a screening visit and will be screened to access eligibility.
Subjects with overweight (25<=BMI<=30kg/m2) and a fasting plasma glucose concentration <7.0mmol/l will be included. Only if all the results from the screening visit are in compliance with the inclusion criteria, subjects can participate in the study.

20 subjects (men and women) will be studied four times with different dietary interventions, in randomized order with at least one week in between. During these periods, they will stay for 36 hours in the respiration chamber. After an overnight stay in the respiration chamber, measurements will start for 24 hours. Glycemic profile (continuous blood glucose monitoring), energy expenditure and substrate oxidation will be measured during the entire period. Profile of insulin, FFA and TAG will be determined over a 14 h period during day time by blood sampling before each meal (breakfast, lunch,diner) and 30,60, 120 and 240 min postprandial. The concentration hydrogen will be measured in end-expiration (alveolar) breath samples every 2h from 8.00h until 22.00h and again at 8.00h the next morning using a gastrolyzer* (Bedfont Scientific Ltd., The Netherlands).

On the four occasions, subjects will receive different dietary treatments, which all consist of 48% of energy as carbohydrate, 37% of energy as fat and 15% of energy as protein.

A. a diet in which the test products contain polydextrose (PDX).
B. a control to diet A where similar test products are given without polydextrose. The test products consist of full available carbohydrates and there is no fiber added.
C. an isocaloric control to diet A where similar test products are given without polydextrose. The test products are the same as for diet B, so with full available carbohydrates and no fiber added.
D. a diet where part of the available carbohydrates in the test products are replaced with Soluble Gluco Fiber (SGF)

Control diets B and C are necessary to investigate whether the effect of the soluble fibers on fat oxidation rate is due to the lower caloric intake or the ability of the fibers to increase the fat oxidation rate. In diet A and D, 30% of the available carbohydrates at breakfast and lunch will be replaced by respectively polydextrose or soluble gluco fiber.

Study burden and risks

Results of the study will provide insight if soluble fibers are capable of improving postprandial fat oxidation. A higher postprandial fat oxidation may result in less lipid accumulation in non-adipose tissues, thereby improving insulin sensitivity and the metabolic profile in the longer term. Risks as the result of participation in this experiment are minimal. Venapunctures can occasionally cause a local haematoma or bruise to occur. Some participants report some pain during venapuncture. Insertion of the CGMS could induce some pain, however no discomfort is expected from carrying this device. Previous studies have shown that wearing the CGMS does not hinder the subject in his normal functioning. Also participants will be asked if they are claustrophobic, because this could become a problem when they are staying in the respiration chamber and will be excluded if no solution can be found. No harm from the dietary intervention is to be expected. All diets used during this study are provided by Tate and Lyle or purchased in the local supermarket and used before indicated expiring dates. During the test days meals will be prepared in the kitchen of the department of Human Biology which is solely dedicated for preparing of food for human use.

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

Overweight men and women (25<=BMI<=30kg/m2), age 20-50 years, fasting glucose <7.0mmol/l

Exclusion criteria

regular smokers, people with intensive fitness training, diabetes mellitus, all medical disorders or medication use that potentially interfere with this trial, claustrophobia, anemia

Study design

Design

Study type: Observational invasive

Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	10-02-2010
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	NL30589.068.09