Postprandial effects of a low vs. a high glycemic index food product on metabolic risk markers in lean and obese men

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The major research question is:Does a low-GI food product improve in healthy and obese men postprandial plasma concentrations of inflammatory markers as compared to a high-GI product?Major null hypothesis, H0:In healthy as well as obese men, a low-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON31524

Source
ToetsingOnline

Brief title
Postprandial effects of low-GI food products on metabolic risk markers

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
fatty degeneration, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Top Institute of Food and Nutrition

Intervention

Keyword: glycemic index, inflammation, lean men, obesity, postprandial effects

Outcome measures

Primary outcome

IL-6

Secondary outcome

Is there a difference between lean and obese subjects in metabolic risk markers

after consuming a low- or high-GI food product?

Study description

Background summary

Dietary carbohydrates (CHO) with different chemical compositions (e.g. sugars, oligosaccharides, starches and nonstarch polysaccharides) and physical structures are digested and absorbed at different rates in the human small intestine, and therefore give rise to different blood glucose and insulin responses. These differences formed the basis of the glycemic index (GI), which was introduced by Jenkins et al. in the early 1980s. It is a measure of the change of blood glucose in healthy lean subjects following ingestion of a fixed quantity of carbohydrates from a food. Some foods result in a marked rise followed by a more or less rapid fall in blood glucose (high-GI foods), whereas others produce a smaller peak along with a more gradual decline in plasma glucose (low-GI foods). The rate of glucose entry into blood and the duration of the elevated blood glucose are known to induce many hormonal and metabolic changes that may affect health and disease parameters. Many experts now consider the manipulation of the dietary GI as a useful tool for the treatment and prevention of chronic diseases typical of industrialized countries. As suggested by large prospective observational studies, including 2 meta-analyses , a higher 120 min post load blood glucose concentrations independently predicts cardiovascular morbidity and mortality in individuals without diabetes. Moreover, randomized dietary intervention trials showed that low-GI diets may be associated with improvements in cardiovascular disease risk factors, including reduced LDL cholesterol and triacylglycerols (TG), and improved insulin sensitivity. Results between studies are however inconsistent.

In our previous intervention study (results not yet published: MEC: 05-139) with overweight subjects the longer-term effects of food products, different in GI, were investigated on fasting glucose and lipid metabolism, and on inflammatory markers. No differential effects of the diets were found on these parameters after one day or after 11 weeks. In general, results of studies on the effects of carbohydrate consumption on inflammatory parameters are controversial. Pereira et al., for example, found that a diet with a low-glycemic load (GL, which is derived from the GI) lowered CRP levels compared to a low-fat diet. Sorensen et al., however, found no effects on CRP concentrations after 10 weeks consumption of an artificial sweetener as compared to sucrose. In these studies, the diets not only differed in GI, but also in fiber, protein, and fat content. Therefore, effects of GI on inflammatory parameters remain controversial. It is, however, also possible that in our intervention study the difference in GI between the diets may have been too small to detect any difference in inflammatory markers. Moreover, it may be more important to look at the postprandial effects of diets with different GIs, because subjects spent most of the day in the postprandial state. Motton et al., however, found in healthy overweight women no increase in monocyte activation of monocytes after consumption of a high GL meal as compared to a low GL meal. Again, the GL was not the only difference between the experimental diets, which may have confounded comparisons. However, it is also possible that the GI or GL of a meal or a diet will influence the inflammatory response in persons who are more sensitive to the carbohydrate content of the diet.
Thus, there is a need to carry out a more controlled postprandial study in obese subjects. Based on these considerations, we want to investigate the postprandial effects of a low-GI vs. high-GI food on inflammatory markers in obese subjects. As already mentioned, the GI is calculated in lean subjects, but low-GI food products are the most useful for overweight and obese subjects because they have an increased risk of developing type 2 diabetes or CVD. Therefore, a second objective is to compare the effects of the GI of a food product on inflammatory markers in lean and obese subjects.

Study objective

The major research question is:
Does a low-GI food product improve in healthy and obese men postprandial plasma concentrations of inflammatory markers as compared to a high-GI product?

Major null hypothesis, H0:
In healthy as well as obese men, a low-GI food product does not lower postprandial plasma IL-6 concentrations when compared with a high-GI food product.

Major alternative hypothesis, Ha:
In healthy as well as obese men, a low-GI food does lower postprandial plasma IL-6 concentrations when compared with a high-GI food.

Minor null hypothesis, H0:
The effect of a low-GI food product vs. a high-GI food product on postprandial plasma IL-6 concentrations is not different between healthy lean and obese men.

Minor null hypothesis, Ha:
The effect of a low-GI food product vs. a high-GI food product on postprandial plasma IL-6 concentrations are more pronounced in healthy obese men as compared to those in healthy lean men.

Study design

This study consists of a randomized, crossover study. 15 lean and 15 obese men (aged 18-65y) will be included. Before the start of the study, subjects will be randomly assigned to one of the three products; both groups will receive a low-GI and a high-GI cookie, and on 2 other test days a glucose solution to enable us to calculate the GI of the cakes. Between each intervention day, a wash-out period of minimal 3 days is included. There are no indications that carry-over effects will occur after a 3-day wash-out period.
The GI of the food products, cookies with different glucose / patent flour ratios (table 2) will be determined, based on standard and accepted protocols. For this, we have based us on the formal protocol recommended by the Food and Agriculture Organization (1998). According to this protocol, healthy people will receive a portion of the cookie containing 50 grams of digestible (available) carbohydrate. After a fasting blood sample, the cookies will be consumed and for the next two hours plasma glucose levels will be measured at defined time points. For each person, the area under the curve (AUC) of plasma glucose levels, corrected for fasting glucose concentration and ignoring concentrations below fasting concentrations, will be calculated for each cookie. On two other occasions, the same people will consume a reference glucose solution (providing the same amount of carbohydrate) and their two-hour blood glucose responses will also be measured. A GI value for the test food is then calculated for each person by dividing their glucose AUC for the test food by their glucose AUC for the reference food (mean of two tests). The final GI value for the test food is the average GI value for all participants. The evening before a test, each subject should consume a meal of his own choice and repeat that same meal before each subsequent test. Subjects will be asked to arrive at the same time for each session. At each test, a standard amount of 250 ml water will be given. The glucose solution is composed of 50 g glucose diluted in 250 ml water.
In both the lean and obese groups multiple measurements will also be made to follow the time course of metabolic risk markers in plasma after eating the low-GI or a high-GI food product. Blood samples will be taken at time 0, 15, 30, 45, 60, 90, 120, 180 and 240 minutes after breakfast. Body weight will be measured each day in the morning. Results will be used to relate GI with markers for low-grade systemic inflammation, endothelial function, as well as with parameters related to glucose and lipid metabolism.
The subjects will record in diaries any signs of illness, medication used, and

any deviations from the protocol. In addition, subjects are urged not to change their level of physical exercise or use of alcohol during the study. The subjects are instructed to keep a stable body weight; therefore at each visit we will record body weight.

Table 1: Experimental design
Product 1* Product 2** Product 3 Product 3
Group lean (N=15) Low-GI cookie High-GI cookie Glucose solution Glucose solution
Group obese (N=15) Low-GI cookie High-GI cookie Glucose solution Glucose solution
** 30 gram of glucose / 10 gram of patent flour
* 0 gram of glucose / 40 gram of patent flour
Products will be provided in random order.

Intervention

2 mornings consumption of low- or high-GI cookie
2 mornings consumption of glucose solution

Study burden and risks

Before the start of the study subjects will be screened to access eligibility (visit duration 30 min). At the screening visit body weight, body length, and waist and hip circumference will be measured. Subsequent, each subject will be randomly allocated to one of the three products (low-GI cake, high-GI cookie or twice a reference glucose solution). In the test period, the subjects will visit the department 4 times. During these visits an indwelling cannula will be inserted in an antecubital vein and when the subjects consume the cookies 9 blood samples (172 mL in total) will be taken during 4 hours. When subjects consume the reference glucose solution 7 blood samples (28 mL in total) will be taken during 2 hours. Total time investment for the subjects will be ± 14 hours. During this period, subjects will be at the university. Blood sampling might cause bruises or haematoma.

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

Lean (BMI 20-25kg/m²) as well as obese (BMI 30-35 kg/m²) non-smoking men, aged 18-65. Because smoking might influence inflammatory parameters we will use non-smokers.

Exclusion criteria

- unstable body weight (weight gain or loss >3 kg in the past 3 months)
- Quetelet-index (BMI) < 20 kg/m2 or > 25 kg/m2 or < 30 kg/m2 or > 35 kg/m2
- diabetes mellitus and anti-diabetic medication (e.g. PPARγ agonists)
- severe medical conditions that might interfere with the study such as hypertension, epilepsy, astma, COPD, inflammatory bowel diseases and rheumatoid arthritis, autoimmune disorders, allergies
- use of medication or a diet known to affect serum lipid levels
- history of coronary heart disease
- abuse of drugs and/or alcohol
- smoking
- women
- use of an investigational product within the previous 30 days
- not willing to give up being a blood donor from 4 weeks before the start of the study and during the study.
- impossible of difficult to venipuncture

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	06-02-2008
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	NL21301.068.07