Blood glucose homeostasis in type 2 diabetes: the effects of sacharose

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The aim of this study is to investigate the glycemic effects of the consumption of soft drinks, under fully standardized nutritional conditions, in obese type 2 diabetes patients and non-obese and obese normoglycemic control subjects.

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

Summary

ID

NL-OMON30531

Source
ToetsingOnline

Brief title
Sacharose and glucose homeostasis

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
non-insulin dependent diabetes mellitus, Type 2 diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: glycemic control, Healthy type 2 diabetes, sacharose

Outcome measures

Primary outcome

glucose concentration

Secondary outcome

24h hyperglycemia.

Study description

Background summary

It is suggested that the consumption of food-stuffs which contain large amounts of sugar increase the risk for the development obesity, insulin resistance and type 2 diabetes through strong increases in postprandial blood glucose concentrations. This assumption has lead to a boom in the sales of so-called light products. However, the actual effect of sugar (sacharose) containing foods-stuffs (e.g. soft drinks) on glycemic variation has not been investigated under real-life conditions.

Study objective

The aim of this study is to investigate the glycemic effects of the consumption of soft drinks, under fully standardized nutritional conditions, in obese type 2 diabetes patients and non-obese and obese normoglycemic control subjects.

Study design

Monitoring of the glucose homeostasis in type 2 diabetes patients and control subjects during a period of 40 hours in which sugarcontaining beverages will be compared with placebo beverages.

Intervention

consumption of sugar containing beverages

Study burden and risks

Screening:
1 x Oral Glucose Tolerance Test (OGTT) of 2 hours
1 x hydrostatic weighing method of 0,5 hour

Test:
The time investment for each subject will be ~80 hours, divided over 2, 2 day periods with each test-day separated by at least 5 days. During these test-days the subjects will remain at the university for approximately 1,5 hours. For the remaining part of the tests the subjects can resume their normal daily activities.

Placement of the venous catheter or the microdialysis fiber can lead to mild discomfort comparable to a normal blood draw. A hematoma could appear on the place of the venapunction or insertion of the microdialysis fiber.
The beverages will contain normal sugar which is a standard additive and is part of the normal diet.

Canceling the diabetes medication for a period of two days results in an increase in blood glucose concentrations but does not result in a serious disturbance of the glucose homeostasis and blood glucose concentrations are normalized within 1-2 days after the screening. After the screening the subject can resume their normal medication routine.

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 NGT Group
· Male
· Age between 40 and 60 years
· Normoglycemic (according to 2006 ADA guidelines)
· BMI < 30 kg/m2;Obese NGT Group
· Male
· Age between 40 and 60 years
· Normoglycemic
· BMI 30- 35 kg/m2 ;Obese Type 2 Diabetes group
· Male
· Age between 40 and 60 years
· BMI 30- 35 kg/m2
· Oral blood glucose lowering medication

Exclusion criteria

· Exogenous insulin use
· Cardiac disease (any cardiac event in the last 5 years)
· HbA1c >10%
· Microalbuminuria: albumin:creatinine ratio >2,5

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2007
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	22-02-2007
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	NL16188.068.07