The effect of vinegar co-ingestion on postprandial glucose control in type 2 diabetes patients.

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The main objective of this study is to assess the acute effect of co-ingested vinegar on postprandial plasma glucose levels in type 2 diabetes patients.

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

Summary

ID

NL-OMON34405

Source
ToetsingOnline

Brief title
Vinegar co-ingestion in type 2 diabetes.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
adult-onset diabetes, type 2 diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hyperglycemia, type 2 diabetes, vinegar

Outcome measures

Primary outcome

Main study parameter/endpoint

• Postprandial plasma glucose concentration

• Postprandial plasma insulin concentration

• Hyperglycemia (glucose concentration >10mmol/L)

Secondary outcome

Secondary study parameters/endpoints

• Energy expenditure (derived from physical activity record)

• Dietary intake (derived from dietary record)

Study description

Background summary

Diet is considered as one of the cornerstones of type 2 diabetes treatment, next to pharmaceutical therapy and exercise. It has been shown that dietary adjustments can strongly improve postprandial glycemia in type 2 diabetes patients. Therefore, there is great interest in dietary modulation to improve postprandial glucose metabolism. Over the last years, vinegar co-ingestion has been shown to reduce postprandial glucose excursions in healthy subjects. However, research on the glucoregulatory benefits of vinegar in type 2 diabetes patients is currently lacking. Furthermore, it is not clear whether vinegar co-ingestion has only sufficient therapeutic strength when ingested with a mixed meal or also with mono-saccharides. Finally, it should be established whether vinegar co-ingestion is an effective strategy to reduce postprandial hyperglycemia under free-living conditions.

Study objective

The main objective of this study is to assess the acute effect of co-ingested

vinegar on postprandial plasma glucose levels in type 2 diabetes patients.

Study design

Three studies will be performed in a single-blind, randomized, cross-over design. Study 1 and 2 consist of 2 test days, separated by 1 week.
Study 3 consists of two 3-day test periods, separated by 1 week.

Intervention

Study 1
During both test days, subjects will ingest a test drink or a placebo drink. The test drink consists of 82,5 g glucose monohydrate dissolved in 225 ml water and 25 ml vinegar. The placebo drink consists of 82,5 g glucose monohydrate dissolved in 250 ml water. The drinks will be offered in a non-transparent drinking bottle.

Study 2
During both test days, subjects will ingest a mixed meal combined with a test drink or a placebo drink. The test drink consists 175 ml water and 25 ml vinegar. The placebo drink consists of 200 ml water.

Study 3
During both test periods, subjects will ingest a standardized diet entirely consisting of commercially available food products. The standardized diet includes 3 meals and 3 snacks per day, which have to be ingested at predetermined times (8:00, 10:30, 13:00, 15.30, 18,00, 20.30 h). Directly prior to each main meal subjects have to ingest a test drink or placebo drink. The test drink consists of 75 ml water and 25 ml vinegar. The placebo drink consists of 100 ml water. Individual energy requirements will be calculated with the Harris and Bennedict equation with appropriate adjustment for subjects* activity level.

Study burden and risks

Study 1
Risks as the result of participation in this experiment are minimal. At the insertion site of the of the intravenous catheter, a hematoma could occur.

Time investment:
screening: 1 hour
test days: 2 x 3 hours

Study 2
Risks as the result of participation in this experiment are minimal. At the insertion site of the of the intravenous catheter, a hematoma could occur.

Time investment:
screening: 1 hour
test days: 2 x 5 hours

Study 3
Risks as the result of participation in this experiment are minimal. At the insertion site of the of the intravenous catheter, a hematoma could occur.

Time investment
screening: 3 uur
test periods: 2 testperiods include 4 visits of 45 minutes

Risks as the result of participation in this experiment are minimal. At the insertion site of the of the intravenous catheter, a hematoma could occur
Only the type 2 diabetes patients participating in study 3 will stop the use of anti-diabetic medication during the last 2 days prior to the OGTT. After the OGTT subjects will resume the use of their prescribed medication. This temporary cessation of oral blood glucose lowering medication is included to assess the *normal* glycemic and insulin responses without interference of oral blood glucose lowering medication. This method of glucose tolerance testing has been applied in our previous protocols (MEC 99-215, 02-077, 03-058, 04-218, 05-028, 06-3-081 & 09-3-028) without any adverse events.

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

Male type 2 diabetes patients:
-40-70 yrs.
-BMI 25-35 kg/m2
-oral blood glucose lowering medication;Male control subjects:
-40-70 jr.
-BMI 25-35 kg/m2

Exclusion criteria

Exogenous insulin therapy; HbA1c <6.5% or >10.0%; diagnosed impaired renal or liver function; morbid obesity (BMI>35 kg/m2); incident cardiovascular events in the last year (heart attack, stroke, aneurysms). Furthermore, subjects with an ulcus pepticum, ulcus duodeni, ulcus ventriculi and/or oesophagal reflux will be excluded. In addition, subjects using antacids, H-2-receptor blockers, proton pump inhibitors, NSAID*s, and/or prokinetic agents will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2010
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	NL32216.068.10