Onderzoek naar de onstekingsremmende werking van aardbeien.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27220

Source
NTR

Brief title
Aardbeienstudie

Health condition

Metbolic syndrome patients with glucsoe intolerance
High-glucose induced inflammation and endothelial dysfunction
Patienten met het metabool syndroom en glucose intolerantie
Hoog-glucose geinduceerde inflammatie en endotheel dysfunctie

Sponsors and support

Primary sponsor: Maastricht University, Research institute Nutrim
Source(s) of monetary or material Support: InnovatieCentrum Gezonde Voeding, Venrayseweg 182
5928 RH Venlo

Intervention

Outcome measures

Primary outcome

1. Glucose-induced production of E-selectin (ELISA), Il-6 (Q-PCR) and IL-1beta(Q-PCR) 2 h after consumption of 75 gram glucose. Timepoint: day 16 vs. day 1;

2. Markers of oxidative stress, i.e. 8-oxodG in PBMC's, malondialdehyde and isoprostanes in blood and urine. Timepoint: day 16 vs. day 1.

Secondary outcome

Glucose tolerance and insulin sensitivity (HOMA-index). Timepoint: day 16 vs. day 1.

Study description

Background summary

Background:
In vitro studies from our lab showed that strawberry extracts exert anti-inflammatory activities, which were associated with concentrations of polyphenols and catechins in the extracts. In addition, recent epidemiologic studies reported inverse relations between the consumption of strawberries and plasma levels of C reactive protein (CRP) and the risk for cardiovascular diseases. These data indicate that regular strawberry consumption in real life situations is also associated with reduced chronic inflammation and cardiovascular disease risk. For other polyphenol and catechin-rich dietary products, i.e. chocolate and green tea, human intervention trials indicated that these products have anti-inflammatory and anti-oxidant activities and improve endothelial and vascular function. Therefore it is hypothesized that regular consumption of strawberries can reduce endothelial dysfunction by reducing inflammation and oxidative stress. This is thought to be mediated by polyphenols and catechins present in strawberries.

Objective:
The aim of the proposed study is to evaluate the effect of daily consumption of 400 gram strawberries as smoothies during 2 weeks on markers of endothelial function, inflammation and oxidative stress.
Study design: The study will be a randomized, single blind, placebo-controlled intervention study.

Study population:
40 metabolic syndrome patients fasting blood glucose levels between 5.5 and 7,8 mmol/l will be selected, aged between 40 and 70 years, both females and males. 20 patients will be randomly assigned to the strawberry group and 20 to the placebo group. Randomization will be done gender specifically, ensuring an equal number of males and females in both study

groups.

Intervention:
The intervention period will be 2 weeks, with 20 patients consuming 400 gram strawberries as 2 smoothies per day, and 20 patients consuming 2 iso-caloric (compared to the smoothies) placebo strawberry lemonades of 200 cl, based on a commercially available lemonade with artificial flavor compounds.

Main study parameters/endpoints:
Markers of endothelial function, inflammation and oxidative stress will be measured after an oral glucose tolerance test (OGTT). The effect of the intervention will be measured on day 16 of the study, to exclude acute effects of strawberry consumption. The estimated outcome is a 25% reduction in the OGTT-induced inflammatory gene transcription.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Participants have to be in a fasting state and visit the laboratory for the prescreening and twice to perform an OGTT. They will consume 2 strawberry or placebo drinks per day during 2 weeks. The evening preceding the OGTT they consume a standard meal. Allergic or hypersensitivity reactions for strawberries can occur, and these are reasons to withdraw from the study.

Study objective

Daily conumption of a portion of 400 gram strawberries will reduce the glucose induced inflammatory response and oxidative stress in metabolic syndrome patients with impaired glucose tolerance (beginning type 2 diabetes).

Study design

OGTT and other measurements are done before start of the intervention on day 1 and repeated on the second day after last consumption of straweberries (day 16).

Intervention

1. Intervention: 400 gram strawberries as smoothies, daily for 14 days;

2. Placebo: 400 gram strawberrie lemonade with equal carbohydrate and protein content as strawberries.

Contacts

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Eligibility criteria

Inclusion criteria

1. Males and females, aged between 40 and 70 years;

2. Fasting blood glucose levels between 5.5 and 7.8 mmol/l, or diagnosed as having mild type 2 diabetes, but not use insulin;

3. Have been diagnosed for the metabolic syndrome i.e. have a waist circumference > 94 cm for men, and > 80 cm for women and one of the following other criteria:

A. Triglycerides > 150 mg/dl, or treatment for this lipid abnormality;

B. HDL cholesterol < 40 mg/dl for men, or < 50 mg/dl for women, or treatment;

C. Blood pressure systolic > 130 mg Hg, diastolic > 85 mm HG, or treatment of or previously diagnosed hypertension.

Exclusion criteria

1. Have or have had hypersensitivity or allergic reactions for strawberries;

2. Use of insulin;

3. Use of anti-coagulation medication such as acenocoumarol;

4. Use of anti-inflammatory medication such as ibuprofen, naproxen, paracetamol, or corticosteroids on a regular basis;

5. Liver or kidney diseases;

6. An acute infection less than 2 weeks ago;

7. Being or have been treated for a malignant disease shorter than 6 months before the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2010
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-04-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34765
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2157
NTR-old	NTR2281
CCMO	NL29884.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34765

Study results

Summary results
N/A