Effect van broccoli zaailingen op ontsteking en insuline gevoeligheid na een testmaaltijd.

No registrations found.

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

Summary

ID

NL-OMON20949

Source
NTR

Health condition

insulin resistance, inflammation

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Food & Nutrition Delta

Intervention

Outcome measures

Primary outcome

The main outcomes of this study are inflammation and insulin sensitivity. Inflammation will be addressed by PBMC activation as measured by nuclear translocation of NF-kappaB, plasma cytokine levels and insulin sensitivity as determined by plasma concentrations of glucose and insulin as well as the uptake of glucose in tissues.

Secondary outcome

Sulforaphane kinetics, measured in plasma and urine.

Study description

Background summary

Meals with a high amount of available carbohydrates result in postprandial hyperglycemia. These glucose spikes can increase in inflammatory parameters. It is hypothesized that recurring postprandial glucose spikes can lead to decreased insulin sensitivity and therefore it is important to prevent postprandial inflammation. Broccoli seedlings are enriched in the isothiocyanate sulforaphane, which is extensively studied as an anticancer agent, but is also reported to possess antioxidant and anti-inflammatory properties. In vitro, we showed that SFN can potently inhibit TNF-Î±-induced NF-kB activation. Therefore, we will test the anti-inflammatory effect of broccoli seedlings on inflammatory parameters after an oral glucose load. Insulin sensitivity will be tested by an oral glucose load four hours after the first load. Furthermore, the kinetics and bioavailability of sulforaphane and related metabolites will be determined.

Study objective

A high-glucose load can lead to inflammation and it is thought that recurring hyperglycemia may lead to insulin resistance. Our aim is to prevent glucose-induced inflammation and decreased insulin sensitivity with broccoli seedlings which are enriched in the bioactive compound sulforaphane.

Study design

Multiple timepoints on one day for PBMC, cytokines, SFN and metabolic factors.

Intervention

Intervention with broccoli seedlings (BroccoCress).

Butter letuce will be used as a control.

Volunteers received 75 gram glucose in 250 mL tap water,
leading to postprandial inflammation as measured by activation of
circulating white blood cells (PBMCs) and plasma cytokines. We will test if
broccoli seedlings, rich in the bioactive compound sulforaphane, can
counteract postprandial inflammation. Butter lettuce will be used as a
control. The study is designed as a randomized, single-blinded, cross-over

explorative intervention study. The intervention existed of two periods with a one week wash-out period in between. Each period, volunteers arrived at the clinic the evening before the experimental day. At the experimental day, the volunteers received broccoli seedlings or butter lettuce.
The effect of broccoli seedlings on glucose sensitivity is another objective in this study and will be assessed by a second oral glucose load.
Furthermore, kinetics and bioavailability of sulforaphane and other metabolites will be studied using 13C labelled broccoli seedlings - 13C is a stable isotope, which poses no threat to human health.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy male volunteer aged 18 to 30 and BMI 18-25 kg/m2, extremities included;

2. Not involved in intensive sportive activities more than twice a week (e.g. playing football, tennis, running, race-cycling, swimming);

3. Stable weight and no intention to lose weight until completion of the study;

4. Signed written informed consent form (ICF).

Exclusion criteria

1. Not being able to fast overnight (10 hours);

2. Vegetarians;

3. Documented Diabetes mellitus or fasting glucose level of >6.1mmol/l at screening;

4. Clinically significant inflammatory disease (possibly interfering with measurement of parameters in this study);

5. Intake of medication (from 2 weeks before screening until the end of the study, except for sporadic use of paracetamol and/or treating an AE);

6. Smoking;

7. Donation of blood within the last 3 months prior to admission to the clinic;

8. Participation to another clinical study within 90 days before enrolment;

9. Positive drug screen or alcohol breath test at D-1;

10. Fear of blood and/or needles;

11. Veins unsuitable for intravenous (i.v.) catheter on either arm (e.g., veins that are difficult to locate, access or puncture, veins with a tendency to rupture during or after puncture);

12. Clinically relevant abnormalities in clinical chemistry, hemoglobin or positive HIV, HbsAg and/or HepC at screening.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-06-2012
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-05-2012
Application type:	First submission

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
NTR-new	NL3290
NTR-old	NTR3435
Other	Food&nutrition delta : FND09002
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A