Effect of broccoli seedlings on postprandial inflammation and insulin sensitivity

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The objective of this study is to investigate the effect of broccoli seedlings on postprandial inflammatory parameters and insulin sensitivity after an oral glucose load (dual isotope technique) and monitoring the bioavailability and kinetics of SFN...

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

Summary

ID

NL-OMON37048

Source ToetsingOnline

Brief title BroccoCress

Condition

• Glucose metabolism disorders (incl diabetes mellitus)

Synonym carbohydrates hyperglycemia

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** UMCG

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Intervention

Keyword: healthy men, Insulin sensitivity, insuline resistancy and inflammation, Single dose

Outcome measures

Primary outcome

Postprandial inflammation will be tested by measuring nuclear NF-*B abundance

in peripheral blood mononuclear cells and by measuring plasma cytokine

concentrations. In addition, postprandial insulin sensitivity will be

determined by measuring plasma concentrations of glucose and insulin as well as

glucose uptake in peripheral tissues using dual isotope labelling.

Secondary outcome

Evaluate the effect of BroccoCress on insulin sensitivity after a 2nd glucose

load

Monitor the bioavailability and kinetics of SFN and related metabolites in

blood and urine

Study description

Background summary

Rationale: Meals with a high amount of available carbohydrates result in postprandial hyperglycemia. These glucose spikes can cause an increase in inflammatory parameters. It is hypothesized that recurring postprandial glucose spikes can lead to decreased insulin sensitivity. Hence, 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 sulforaphane can potently inhibit TNF- α induced NF-*B activation. Therefore, we will test the anti-inflammatory effect of broccoli seedlings on postprandial inflammatory parameters after an oral glucose load. Insulin sensitivity will be tested by an oral glucose load four hours after the first glucose load. As the study concerns normal food products,

no preclinical or toxicological studies are performed with the used test meals.

Study objective

The objective of this study is to investigate the effect of broccoli seedlings on postprandial inflammatory parameters and insulin sensitivity after an oral glucose load (dual isotope technique) and monitoring the bioavailability and kinetics of SFN and related metabolites in blood and urine.

Study design

Randomized, singe-blind, cross-over, exploratory intervention study

Intervention

Part A;

12 volunteers will participate in the study; each person will be studied on two different occasions at least one week apart, consuming 8 gram butter lettuce (Lactuca sativa var. Capitataor) or 8 gram BroccoCress. 45 minutes after either lettuce or BroccoCress a first glucose load (75 gram glucose) will be ingested, followed by a second load of 75 gram naturally 13C enriched glucose, 4 hours after the first glucose load.

Part B;

4 volunteers will participate in the study; each person will be studied on one occasion, consuming 8 gram BroccoCress (of which 4 gram will be labelled with 13C). 45 minutes after BroccoCress a first glucose load (75 gram glucose) will be ingested, followed by a second load of 75 gram glucose, 4 hours after the first glucose load

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The volunteers need to stay a night and a day in the research institute on two different occasions. There will be two catheters inserted, one for an infusion of labelled glucose and one for blood collection. Per study day 250 mL blood will be collected at maximum, thus in total 500 mL at maximum. In addition urine samples will be collected. The test drinks (glucose, BroccoCress or lettuce) are food products which are not posing any risk to the health of the volunteers. The volunteers will fill in a questionnaire concerning habitual food intake, smoking, sportive activities and family history of T2DM

Contacts

Public Universitair Medisch Centrum Groningen

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Center for Medical Biomics, Antonius Deusinglaan 1 Groningen 9713 AV NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

healthy men

Exclusion criteria

Clinical singificant abnormalities at medical research Diabetes mellitus

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Study design

Design

| Study type: | Interventional |
|---------------------|-------------------------------|
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

Recruitment

| NL | |
|---------------------------|---------------------|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-06-2012 |
| Enrollment: | 16 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|---|
| Date: | 22-05-2012 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO | |
| Date: | 22-06-2012 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

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 CCMO **ID** NL40658.056.12