The effect of 2 weeks of chicory root fibre supplementation on energy intake.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29476

Source
Nationaal Trial Register

Health condition

eating behaviour

Sponsors and support

Primary sponsor: Wageningen University, Division of Human Nutrition

Source(s) of monetary or material Support: Carbohydrate competence center (CCC)

Intervention

Outcome measures

Primary outcome

Primary Objective:

To study the effects of 2 week supplementation of 10g fibre out of CRP on energy intake in healthy subjects.

Secondary outcome

Our secondary objectives are to investigate whether these effects co-exist with changes in feelings of satiety, glucose, leptin, insulin responses, changes in fermentation activity and changes in immunological parameters (i.e. faecal parameters, and immunological parameters in blood) to explore underlying biological mechanisms.

Glucose, leptin, insulin responses, changes in fermentation activity and changes in immunological parameters will only be determined in a subsample of the pupulation: n=20.

Study description

Background summary

Background of the study: It is known that some dietary fibers are beneficial for health. Some dietary fibres are associated with body weight management and others are associated with immunological benefits. Chicory root is a good source of fiber and it contains different fibre types. After the majority of the fibre type ‘inulin’ is extracted from the chicory root for commercial usage in food products, a mixture of fibres is left over: dried chicory root pulp (CRP). It is hypothesized that consumption of a product with CRP may reduce energy intake on a longer term, as a consequence of increased feelings of satiety when compared to a control product.

Objective: To study the effects of 2 weeks of supplementation with CRP compared to a control product in healthy subjects on energy intake, possible underlying mechanisms and effects on immunological parameters.

Study design: Double blind, randomized cross-over trial with 2 interventions

Study population: 46 healthy, unrestrained men and women, BMI 18.5-25 kg/m2, age 18-40y.

Intervention: Each subject will ingest two times 16 subsequent days either five control bars or five bars with added CRP on top of their regular diet. In between the two interventions there is a wash out period of 2 weeks. Subjects will eat two small bars as midmorning snack between breakfast and lunch, and three small bars as afternoon snack between lunch and dinner. During the treatment period with the CRP-bars subjects will consume an additional 10g of fibre out of CRP per day. The control bar is composed of similar ingredients as the CRP bar, except for the added CRP.

Primary parameter: The first 48hrs and the last 48hrs of each treatment period ad libitum energy intake will be measured. The primary outcome is the difference in the change in energy intake after 2 weeks of dietary fibre supplementation vs. 2 weeks of control bar supplementation.

Secondary parameters:

- Differences in 24hrs feelings of satiety,

- Body weight.

In a subsample of the study population we will also measure:

- Fasting blood samples: glucose, insulin, leptin, and immunological parameters

- Faecal samples: to measure composition of microflora, SCFAs and IgA levels

- Hydrogen in breath samples: as a measure of fermentation activity

Study objective

We expect that there will be a difference in energy intake after 2 weeks of supplementation of a bar with 10g added fibre out of chirory root pulp (CRP) compared to 2 weeks of supplementation of a control bar. We hypothesize that the energy intake will be lower after 2week supplementation of a bar with CRP compared to 2 week supplementation with the control bar.

Study design

• Energy intake will be measured during controlled ad libitum periods (48hrs at baseline, and 48hrs at the end of each intervention period).

• 24h satiety scores will be measured hourly on one day at baseline of an intervention period and one day at the end of an intervention period.

• Body weight will be measured 1x at baseline, 1x in the middle, and 1x at the end of each intervention period

• Fasting blood samples will be taken 1x at baseline and 1x at the end of each intervention period

• Hydrogen production (as a measure of colonic fermentation), will be measured by collecting breath samples hourly on one day at baseline and at one day at the end of each intervention period.

• Faecal samples will be collected at baseline and at the end of each intervention period.

Intervention

This study will be a double blind, randomized cross-over trial with 2 interventions. Each subject will ingest two times 16 subsequent days either control supplements or supplements with added CRP on top of their regular diet as mid-morning and mid-afternoon snack.
The two study periods will be separated by a two-week washout.

The supplements will be a muesli bar with added CRP (CRP bar) or without added CRP (control bar). Subjects will eat the CRP-bars or the control bars on two moments a day during the two weeks of supplementation. Subjects will consume 2 small bars as midmorning snack between breakfast and lunch, and 3 small bars as afternoon snack between lunch and dinner. Each small CRP-bar will contain 2g fibre out of CRP. Subjects will eat 5 bars a day, so during the treatment period with the CRP-bar subjects will consume an additional 10g of fibre out of CRP. The control bar is composed of similar ingredients as the CRP bar, except for the added CRP.

Contacts

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Eligibility criteria

Inclusion criteria

• Age: 18-40 year

• BMI: 18.5-25 kg/m2

• Healthy: as judged by the participant

• H2 producer (if they are part of the subsample of 20 subjects)

• Having signed the informed consent form.

Exclusion criteria

• Weight loss or weight gain of more than 5 kg during the last 2 months

• Using an energy restricted diet during the last 2 months

• Lack of appetite for any reason now or during the last 2 months

• Restrained eater: for men >2.89 and for women >3.39, measured by the Dutch Eating Behaviour Questionaire

• Smoking

• Heavy alcohol use: >5 drinks/day

• Pregnant or lactating women (current or the last 6 months)

• Reported stomach or bowel diseases or disorders (e.g. irritable bowel syndrome)

• Reported diabetes

• Reported thyroid disease or any other endocrine disorder

• Using medication other than birth control, paracetamol, acetylsalicylic acid (aspirin), hay fever, and asthma

• Antibiotic use <6 months before the study

• Reported intolerance, allergy, or not liking of the research foods

• Vegetarian

• Current use or usage during the last 2 months of prebiotics or dietary fibre supplements

• Fasting glucose levels >5.8 mmol/l (if they are part of the subsample of 20 subjects)

• Working at or doing an MSc. thesis at the Division of Human Nutrition of Wageningen University

• Volunteers who participated in the Matrix study (NTR3601)

• Subjects who (are planning to) participate in another scientific study during the period in which this nutritional study is performed

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2013
Enrollment:	46
Type:	Actual

Ethics review

Positive opinion

Date:	20-08-2013
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	NL3846

Register	ID
NTR-old	NTR4131
Other	MEC Wageningen 13/06 VeFer studie : ABRnr 44985
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A