The effect of dairy consumption on metabolism and health.

No registrations found.

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

Summary

ID

NL-OMON20152

Source
Nationaal Trial Register

Health condition

Insulin resistance, Type 2 Diabetes Mellitus, metabolic health.

Insuline resistentie, Type 2 Diabetes Mellitus, metabole gezondheid.

Sponsors and support

Primary sponsor: Public-Private Partnership-TKI Agro & Food
Project: ‘Basisvoedingsmiddelen- en gedragsinterventies in relatie tot behoud van gezondheid’ (TKI-AF-12104)
Partners deelproject ao UMCG, FrieslandCampina.
Source(s) of monetary or material Support: Public-Private Partnership-TKI Agro & Food

Intervention

Outcome measures

Primary outcome

As an indicator of metabolic flexibility the change in RQ (ÄRQ) during each challenge test (OGTT and subsequent fasting) will be measured during the test day (wk 6). This parameter relates to the change in substrate oxidation (fatty acids vs. glucose).

Secondary outcome

The glycemic and insulinemic response during an OGTT and subsequent fasting.

The differences in glucose kinetics and insulin sensitivity during an OGTT between the different test periods (high and low dairy diet).

Additional secondary outcomes include (1) blood pressure (2) uric acid, (3) micronutrient intake and status, particularly vitamin B12 status, markers of one carbon metabolism, choline metabolism, riboflavin, and tryptophan metabolism, including tryptophan-kynurenine pathway metabolites, serotonine metabolites and melatonine metabolites, (4) markers of dairy intake, (5) markers of kidney function, (6) markers of bone turnover and calcium homeostasis, (7) markers of oxidative stress, (8) markers of inflammation, and (9) gut microbiota composition and urinary excretion of microbiota fermentation products.

Study description

Background summary

This study aims to investigate the effect of high versus low dairy intake on metabolic fexibility, insulin sensitivity and glucose metabolism in middle-aged, overweight individuals.

Study objective

We will investigate the effects of high dairy intake on metabolic flexibility, glucose metabolism and insulin sensitivity, which are all important characteristics of (metabolic) health. We hypothesize that high dairy intake improves insulin sensitivity, glucose tolerance and metabolic flexibility in a population at risk.

Study design

After each 6 wk period the glucose metabolism and metabolic flexibility of the volunteers will be tested with an oral glucose challenge and a fasting period. During this day several indirect calorimetry measurements will be performed and blood samples will be collected (first every 15 min, later hourly).

Intervention

High dairy (5-6 portions/day) vs low dairy (<1 portion/day), for a 6 week period each. Portion sizes are 250 ml for (butter)milk, 200 g for yoghurt and 30 g (one slice) of cheese.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy male or postmenopausal female volunteer

2. Middle-aged: between 45 and 65 yrs of age

3. BMI > 25 to < 30 kg/m2

4. Low-medium dairy consumer (based on VCP, assessed by questionnaire on health and lifestyle)

5. Used to consume 3 main meals a day including breakfast

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

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

8. Able to participate and willing to comply with study procedures and restrictions

9. Signed written informed consent form (ICF)

Exclusion criteria

1. Diabetes mellitus (based on fasting glucose and HbA1c-values at screening)

2. Clinically relevant abnormalities in blood lipids (total cholesterol > 8 mmol/L, triglycerides > 6 mmol/L, LDL > 5.7 mmol/L) at screening

3. Clinically relevant abnormalities in hematology (a.o. Hb < 8,7 mmol/L) at screening

4. Clinically relevant abnormalities in markers for liver (ALAT, ASAT) and kidney (creatinine-albumin ratio, urine) damage at screening

5. Positive HIV, HbsAg and/or HepC at screening

6. Not being able to fast overnight (12 hours)

7. Unable to resign from smoking during test day (12h) without symptoms of withdrawal

8. Gastrointestinal disorders or undergone digestive tract surgery (except appendectomy)

9. Intake of nutritional supplements (from screening until the end of the study)

10. Use of medication (from screening until the end of the study) that, in the opinion of the investigator/physician, would interfere with the study parameters: oral anti-diabetics, insulin, lipid-lowering drugs (from screening until the end of the study) and anti-biotics (from 1 month before screening).

11. Reported slimming or medically prescribed diet

12. Reported vegan, vegetarian or macrobiotic life-style

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2014
Enrollment:	52
Type:	Actual

Ethics review

Positive opinion

Date:	11-11-2014
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	NL4694
NTR-old	NTR4899
Other	Protocol nr: NL2014.UMCG.N190, ABR nr: NL47643.042.14 : METc nr: METc 2014/298

Study results