The effect of dairy consumption on metabolism and health.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20152

Bron
Nationaal Trial Register

Aandoening

Insulin resistance, Type 2 Diabetes Mellitus, metabolic health.

Insuline resistentie, Type 2 Diabetes Mellitus, metabole gezondheid.

Ondersteuning

Primaire 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.
Overige ondersteuning: Public-Private Partnership-TKI Agro & Food

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-11-2014
Aantal proefpersonen:	52
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4694
NTR-old	NTR4899
Ander register	Protocol nr: NL2014.UMCG.N190, ABR nr: NL47643.042.14 : METc nr: METc 2014/298

Resultaten