Real-time Amino acid Profiling 2

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It is expected that differences in energy density of the study products will modulate the protein digestion profile of dairy proteins in elderly

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

Samenvatting

ID

NL-OMON28579

Bron
Nationaal Trial Register

Verkorte titel
RAP-2

Aandoening

Protein Digestion Kinetics

Ondersteuning

Primaire sponsor: FrieslandCampina Nederland BV
Overige ondersteuning: NL72926.028.20

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to investigate postprandial amino acid kinetics in blood after consumption of concentrated protein products in small volumes providing different (blends of) dairy proteins, with different energy content densities in an older population

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In 2018, at the request of FrieslandCampina, NIZO food research performed a study to compare the effects of consumption of protein drinks containing different sources and blends of dairy proteins in a small volume on postprandial amino acid concentrations in blood in an older population (RAP study; NL65184.072.18). In this study it was shown that consumption of the different concentrated high-protein products resulted in different blood amino acid profiles. Modulation of postprandial amino acid concentrations is considered to be relevant in relation to muscle protein synthesis. A protein blend based on micellar casein and whey protein & hydrolysates, showed, in the RAP study, a surprisingly fast digestion profile. A fast and sufficient rise of amino acids in blood after consumption of these proteins may stimulate muscle protein synthesis especially in older adults. Moreover, malnourished older adults need additional energy intake. Experts recommended recently that older patients with malnutrition or at risk of malnutrition should receive supplements proving 400 kcal and 30 grams of protein per day after hospital discharge. It is known, however, that energy density of products can impact the digestion rate. Therefore, it is relevant to study protein drinks with different energy densities, which can be used in applications for different target groups.

Objective: The primary objective is to investigate postprandial amino acid kinetics in blood after consumption of concentrated protein products in small volumes providing different (blends of) dairy proteins, with different energy content densities in an older population. The secondary objectives of the study is to investigate postprandial glucose and insulin kinetics in blood after consumption of concentrated protein products in small volumes providing different (blends of) dairy proteins, with different energy content densities in an older population.

Study design: The study is designed as a randomized, single-blinded within-subject (cross-over) trial in which a group of 12 subjects receive 6 different dairy products. Each subject will receive all treatments on the same day (± 1 day) of the week with a 1 week (± 1 day) washout period between treatments.

Study population: Apparently healthy non-smoking men and women age ≥65 and ≤80 and BMI ≥20 and ≤32 kg/m2
Intervention: All subjects in this study, will consume different (blends of) dairy protein in small serving size with different energy contents with whey and casein as reference products.

Main study parameters/endpoints: Blood amino acid concentrations before and at 13 time points (up till 5 hours) after consumption of the dairy products.

Doel van het onderzoek

It is expected that differences in energy density of the study products will modulate the protein digestion profile of dairy proteins in elderly

Onderzoeksopzet

Blood amino acid concentrations in blood before and at 13 time points (up till 5 hours) after consumption of the dairy product
Glucose and insulin concentration in blood before and at 9 time points (up till 5 hours) after consumption of the dairy product

Onderzoeksproduct en/of interventie

All subjects in this study, will consume different (blends of) dairy protein n small serving size with different energy contents with whey and casein as reference products.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Age ≥65 and ≤80
• BMI ≥20 and ≤32 kg/m2
• Non-smoking
• Healthy as assessed by the NIZO lifestyle and health questionnaire (“Verklaring leefgewoonten en gezondheid”) and according to the judgment of the study physician.

• Regular and normal Dutch eating habits as assessed by the NIZO lifestyle and health questionnaire (3 main meals per day)
• Veins suitable for cannulation (blood sampling)
• Voluntary participation
• Having given written informed consent
• Willing to comply with study procedures
• Accept use of all encoded data, including publication, and the confidential use and storage of all data for 15 years.
• Accept disclosure of the financial benefit of participation in the study to the authorities concerned

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before day 1 of this study
• Having a history of medical or surgical events that may significantly affect the study outcome, including: Inflammatory bowel disease, hepatitis, pancreatitis, ulcers, gastrointestinal or rectal bleeding; major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy, or bowel resection; known or suspected gastrointestinal disorders, colon or GI tract cancer
• Use of the following medication: glucose lowering drugs, insulin; medication that may impact gastric emptying (e.g. gastric acid inhibitors or laxatives)
• Diagnosed with diabetes, being treated for high blood glucose or increased fasting blood glucose (> 7 mmol/l in finger prick blood) as assessed during screening visit
• For men: Hb <8,5 mmol/l as assessed during screening visit; for women: Hb <7,5 mmol/l
• Use of protein supplements
• Mental status that is incompatible with the proper conduct of the study
• A self-reported reported food allergy or sensitivity to dairy ingredients
• Alcohol consumption for men > 28 units/week and >4/day; for women: >21 units/week and >3/day
• Reported unexpected weight loss or weight gain of > 3 kg in the month prior to pre-study screening, or intention to lose weight during the study period
• Reported slimming or medically prescribed diet
• Recent blood donation (<1 month prior to Day 01 of the study)
• Not willing to give up blood donation during the study
• Personnel of NIZO food research and FrieslandCampina, their partner and their first and second degree relatives
• Not having a general practitioner
• Not willing to accept information-transfer concerning participation in the study, or information regarding his or her health, like laboratory

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-11-2020
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-09-2020
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	NL8951
Ander register	METC Brabant : P2009

Resultaten