Amino acids in the blood after intake of high-protein dairy products

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The objective of this study is to determine the EAA bioavailability in the blood circulation after ingestion of three high-protein dairy products, that differ in their AA composition

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57512

Source
Onderzoeksportaal

Brief title
Effects of the whey to casein ratio in high-protein, yogurt-cultured, dairy products on postprandial blood amino acid bioavailability

Condition

- Other condition

Synonym
Not applicable (healthy volunteers)

Research involving
Human

Sponsors and support

Primary sponsor: Danone Global R&I Center
Source(s) of monetary or material Support: Danone Global R&I Center

Intervention

- Food (substances)

Explanation

N.a.

Outcome measures

Primary outcome

To determine during the 5-hour postprandial period following ingestion of three high-protein, yogurt-cultured, dairy products the maximum concentration (Cmax) of essential amino acids in the blood circulation.

Secondary outcome

To determine during the 5-hour postprandial period following ingestion of three high-protein, yogurt-cultured, dairy products: The Cmax of serum or plasma total amino acids (TAAs), non-essential amino acids (NEAAs), and branch-chain amino acids (BCAAs) . The amount of leucine, EAA, TAA, NEAA, and BCAA concentrations appearing in the serum/plasma (iAUC) during the full postprandial period (iAUC0-300), early phase postprandial period (iAUC0-120), and late phase postprandial period (iAUC120-300). The time at which maximum serum/plasma leucine, EAAs, TAAs, NEAAs, and BCAAs concentrations occur (Tmax). Correlation coefficients between postprandial Cmax and iAUC of serum/ plasma leucine concentrations and amount of whey ingested (absolute amount [g] and amount corrected for body weight [g/kg]). Appetite-related measurements (satiety, fullness, hunger, and prospective food consumption), and their Composite Satiety Score (CSS).

Study description

Background summary

The ingestion of dietary protein increases muscle protein synthesis rates. The anabolic properties of a dietary protein source are determined in large part by its amino acid (AA) composition and digestion and AA absorption characteristics. Plasma essential AA (EAA), availability has been well established as a key modulatory factor for stimulating muscle protein synthesis rates.

High-protein dairy products are increasingly available on the market. These high-protein dairy products can contain up to 70% of its energy content as protein, and vary in the

amount of EAAs they contain.

Study objective

The objective of this study is to determine the EAA bioavailability in the blood circulation after ingestion of three high-protein dairy products, that differ in their AA composition

Study design

This study applies a randomized, open-label, crossover, single-center, exploratory design.

Intervention

3 high-protein, yoghurt-cultured dairy products that vary in the amount of EAAs they contain.

Study burden and risks

All study products are intended to be consumed by general population, therefore there is no safety concern with the use of the study products in healthy volunteers in this study. The protein products that will be tested in this study are safe for human consumption and are commercially available in supermarkets as ‘over the counter’ products. There are no known undesirable effects after intake of the study products. The amount of protein consumed per study visit (20 grams) is approximately one third to one fourth of the daily recommended intake of protein for an average adult. Therefore, there are no serious tolerance issues or other safety issues to be expected with the amounts used in this study.

Contacts

Scientific
Danone Global R&I Center
E. Gerrits
Uppsalalaan 12
Utrecht 3584CT
Netherlands
+31642992789
Public
Danone Global R&I Center
E. Gerrits
Uppsalalaan 12
Utrecht 3584CT
Netherlands
+31642992789

Trial sites

Trial sites in the Netherlands

Nutrition Clinical Research Unit (NCRU)
Target size: 15

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age ≥ 18 and ≤ 40 years at the time of ICF signature
2. Body Mass Index (BMI) ≥ 18.5 and ≤ 29.9 kg/m2
3. Signed informed consent
4. Willingness and ability to comply with the protocol
5. Judged by the Investigator to be in good health

Exclusion criteria

1. Any known surgery or ongoing medical condition that interferes significantly with protein absorption and digestion, and/or gastrointestinal (GI) function (e.g. phenylketonuria, pancreatitis, short bowel syndrome, inflammatory bowel disease, gastroesophageal reflux disease, celiac disease, gastric ulcer, chronic gastritis, gastrointestinal cancer, oesophageal and/or gastric surgery), in the opinion of the investigator.
2. Known renal or hepatic diseases that may interfere with protein metabolism, including but not limited to acute hepatitis, chronic liver disease, nephritis, cystinuria, chronic kidney disease, in the opinion of the investigator.
3. Use of systemic medication within the past 3 weeks prior to screening which in the opinion of the investigator may influence gastric acid production and/or gastrointestinal motility or function and/or protein metabolism (for example: antibiotics, anticonvulsants, prokinetics, antacids or gastric acid inhibitors, opioid analgesics, anticoagulants, corticosteroids, laxatives, growth hormone, testosterone, immunosuppressants, or insulin).
4. Known Diabetes Mellitus type I or type II, insulin resistance, or metabolic syndrome.

5. Any ongoing cancer and/or cancer treatment (except for non-melanoma skin cancer or carcinoma in situ).
6. Known anaemia.
7. A blood donation within 56 days (8 weeks) for men; or 122 days (4 months) for women; prior to the screening.
8. Any known bleeding disorder.
9. Adherence to a strict dietary regime (e.g. vegetarian/ vegan/ paleo/ketogenic/ intermittent fasting/ high protein diet (>1.6 g/kg body weight/day) or a weight loss program.
10. Any known allergies or intolerances to ingredients of the study product, i.e. cow's milk allergies, lactose intolerance.
11. Known pregnancy and/or lactation.
12. Current smoking / vaping/ use of e-cigarette or stopped smoking for < 1 month prior to screening (except for incidental smoking of ≤ 3 cigarettes/ e-cigarettes/cigars/pipes per week on average in the last month prior to screening).
13. Average alcohol use of > 21 glasses per week for men or > 14 glasses per week for women (on average during the last 6 months prior to screening).
14. Drug or medicine abuse in opinion of the investigator.
15. Current eating disorder, e.g. anorexia nervosa, bulimia nervosa, binge eating disorder.
16. Use of protein, amino acid, or creatine supplements within 4 weeks prior to screening.
17. Known difficulties with placement of and/or blood drawings from a cannula.
18. Participation in any other clinical study with investigational or marketed products concomitantly or within four weeks before study visit 1.
19. Major medical or surgical event requiring hospitalization within the preceding 3 months and/or scheduled in the period of study participation relevant in the opinion of the investigator.
20. Investigator's uncertainty about the willingness or ability of the participant to comply with the protocol requirements.
21. Employees of Danone Research and of the investigational site and/or their family members or relatives.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-06-2025
Enrollment:	15
Duration:	2 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO

Date:	24-04-2025
Application type:	First submission
Review commission:	METC Stg BEBO

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
Research portal	NL-009439