Amino acids in the blood after consuming yogurt with extra proteins and milk

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The present study compares the postprandial amino acid uptake kinetics between a commercially available (fermented) yoghurt versus a commercially (full fat pasteurized) milk matched for protein and volume.

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

Summary

ID

NL-OMON57490

Source
Onderzoeksportaal

Brief title
Postprandial blood amino acid availability of a yogurt-cultured, ultra-filtered milk product vs generic milk.

Condition

- Other condition

Synonym
Amino acids, Yoghurt, Milk

Research involving
Human

Sponsors and support

Primary sponsor: Danone Global Research and Innovation Center
Source(s) of monetary or material Support: Danone Global Research and Innovation Center

Intervention

- Food (substances)

Explanation

N.a.

Outcome measures

Primary outcome

To compare the maximum concentration (Cmax) of serum or plasma essential amino acids (EAA) during the 5-hour period following ingestion of study product A versus study product B.

Secondary outcome

To compare between study product A and study product B, during the 5-hour period following ingestion: the relative amount (incremental area under the curve, iAUC) of EAA appearing in the serum/plasma circulation during the full postprandial period (iAUC0-300), early-phase postprandial period (iAUC0-120), and late-phase postprandial period (iAUC120-300)
the iAUC0-300, iAUC0-120, iAUC120-300 and Cmax of serum/plasma leucine, total amino acids (TAA), branch-chain amino acids (BCAA), and non-essential amino acid (NEAA) concentrations
the time point of maximum concentrations (Tmax) of serum/plasma EAA, leucine, TAA, BCAA, and NEAA.

Study description

Background summary

The ingestion of dietary protein increases muscle protein synthesis rates. It has been shown that the magnitude of the muscle anabolic response following protein ingestion is modulated by the amount, the type, and processing of ingested protein. The anabolic properties of a dietary protein source are determined in large part by its amino acid composition and digestion/absorption characteristics. For instance, the increase in post-prandial plasma essential amino acid (and leucine) availability has been well established as a key modulatory factor for stimulating muscle protein synthesis rates.

Milk protein, and its isolated protein components whey and casein, are the most well characterized proteins with regards to their post-prandial plasma amino acid availability and capacity to stimulate muscle protein synthesis rates. In fact, numerous studies have reported

rapid increases in plasma amino acid availability and robust increases in muscle protein synthesis rates following the ingestion of different milk protein isolates and concentrates in various settings. However, far less information is available on the impact of milk proteins within whole-food dairy products on post-prandial plasma amino acid availability.

In typical dietary habits, protein is primarily consumed through protein-rich whole-food products rather than protein isolates or concentrates. Whole-food products contain a variety of nutrients within a complex structure that can influence digestion and nutrient absorption. Additionally, the methods of preparation and processing (e.g., heating, fermentation, centrifugation) and nutrient fortification (e.g., protein enrichment) can affect not only the protein content but also the post-prandial nutrient availability of these products. For instance, whole milk contains 20% of its energy content (En%) as protein, whereas fermented dairy products like yogurt can contain up to 70% En% as protein.

Changes in the properties of whey and casein due to fermentation have been hypothesized to impact post-prandial plasma amino acid availability. However, studies evaluating post-prandial plasma amino acid availability from whole-food dairy products are currently limited. One recent study reported higher post-prandial plasma amino acid concentrations in processed dairy products (ultra heat-treated milk and yogurt) compared to an isonitrogenous amount of pasteurized milk in healthy older adults [10]. It remains to be determined whether other processed whole-food dairy products, such as high-protein fermented yogurt, similarly impact post-prandial plasma amino acid concentrations. High-protein fermented yogurt products are increasingly commercially available in response to a recent surge in consumer demand of high-protein products.

Therefore, the present study aims to compare post-prandial plasma amino acid availability following the intake of a high protein fermented dairy product compared to full fat pasteurized milk.

Study objective

The present study compares the postprandial amino acid uptake kinetics between a commercially available (fermented) yoghurt versus a commercially (full fat pasteurized) milk matched for protein and volume.

Study design

This study applies a randomized controlled, open-label, crossover, single-center, proof of concept design.

Intervention

yogurt-cultured, ultra-filtered milk product

generic full fat pasteurized milk

Study burden and risks

Both 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 both widely commercially available in supermarkets as ‘over the counter’ products. There are no known undesirable effects after intake of the study product (both test and control product). 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. There might be some GI related discomfort after consuming a bolus of study product, such as belching, feeling of fullness, or possibly nausea since the volume of both study products to be taken within the 10 minutes may be not common use for the study participants.

Contacts

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Trial sites

Trial sites in the Netherlands

EB Medical Research
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:	Crossover

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-05-2025
Enrollment:	15
Duration:	2 months (per patient)
Type:	Actual

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:	19-03-2025
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-009375