Determination of the postprandial amino acid uptake kinetics of Yoghurt vs Milk: A randomized controlled clinical trial in health individuals - A bioavailability study

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The present study compares the postprandial amino acid uptake kinetics between a commercially available (fermented) yoghurt vs a commercially available (pasteurized) milk matched for protein, and small differences on fat, calories, and volume.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57064

Source
ToetsingOnline

Brief title
Nutraferm

Condition

- Other condition

Synonym
Not applicable

Health condition

Gezonde deelnemers, dus geen aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Danone Global Research & Innovation center

Intervention

Keyword: Amino acids, Milk, Yoghurt

Outcome measures

Primary outcome

To compare product A vs product B by means of total postprandial blood amino acid concentrations expressed as incremental Area Under the Curve iAUC.

Secondary outcome

o compare product A vs product B by means of essential postprandial blood amino acid (EAA) concentrations expressed as incremental Area Under the Curve iAUC.

To compare product A vs product B by means of maximum incremental concentration (iCmax) of total postprandial blood amino acids (TAA) and as time until maximum concentration (Tmax).

To compare product A vs product B by means of maximum incremental concentration (iCmax) of essental postprandial blood amino acids (EAA) and as time until maximum concentration (Tmax).

Study description

Background summary

Milk is the first source of protein consumed by humans as neonates, and later

in life milk is still an important source of protein in the human diet past infancy. Dairy proteins can be either consumed as the milk product itself but may also be consumed as yoghurt, cheese, or in further processed food products containing milk proteins as an ingredient. Yoghurt is a fermented milk and fermented foods in general gained interest in the past decade related to potential benefits. Fermented dairy products in particular have received attention for their potential to impact human health.
Protein uptake kinetics is not only dependent on pH but is also influenced by a number of other factors. Horstman & Huppertz described that Amino Acid availability is affected by gastric emptying which in turn can be altered by heat treatment, fat content, calorie density, casein content, and homogenization of milk among others. Based on these factors it could be hypothesized that yoghurt would result in faster gastric emptying and thus in improved amino acid uptake kinetics as compared to milk.

Study objective

The present study compares the postprandial amino acid uptake kinetics between a commercially available (fermented) yoghurt vs a commercially available (pasteurized) milk matched for protein, and small differences on fat, calories, and volume.

Study design

This study adopts a randomised controlled, open-label, crossover, single-centre proof of concept design.

Intervention

Two study products will be investigated, both commercially available dairy products being a fermented milk product and a non-fermented milk product:

Product A: Yoghurt

Product B: 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 both *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 dose for an

average adult. Therefore, there are no serious tolerance issues or other safety issues to be expected with the amounts used in this clinical 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 (+/-5 min) may be not common use for the study participants.

Contacts

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Trial sites

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 <= 27.0 kg/m2

3. Written 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 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).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	16
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	25-10-2024
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL87793.056.24