Amino acid concentrations in serum after intake of plant based protein sources

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The aim of this research is to find out more about the speed at which different types of proteins are digested and absorbed into the blood. This is important because differences in the rate of digestion and absorption can affect the nutritional...

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

Summary

ID

NL-OMON56237

Source
ToetsingOnline

Brief title
Plantino I and II

Condition

- Other condition

Synonym
niet van toepassing

Health condition

Biobeschikbaarheid

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research BV

Intervention

Keyword: Amino acid, Bioavailability, Plant Based, Protein

Outcome measures

Primary outcome

Sub-study Plantino I:

Relative content of amino acids in dietary protein and relative amount of amino acids appearing in the blood for the 4 hour period after the ingestion of product A or B versus product C or D and for product A versus product B:

amino acid (x) content product A [g/100g protein] / amino acid (x) content product C [g/100g protein]

and

amino acid (x) iAUC0-240 product A [µmol/L*min] / amino acid (x) iAUC0-240 product C [µmol/L*min]

amino acid (x) content product A [g/100g protein] / amino acid (x) content product D [g/100g protein]

and

amino acid (x) iAUC0-240 product A [µmol/L*min] / amino acid (x) iAUC0-240 product D [µmol/L*min]

amino acid (x) content product B [g/100g protein] / amino acid (x) content product C [g/100g protein]

and

amino acid (x) iAUC0-240 product B [µmol/L*min] / amino acid (x) iAUC0-240 product C [µmol/L*min]

amino acid (x) content product B [g/100g protein] / amino acid (x) content product D [g/100g protein]

and

amino acid (x) iAUC0-240 product B [µmol/L*min] / amino acid (x) iAUC0-240 product D [µmol/L*min]

amino acid (x) content product A [g/100g protein] / amino acid (x) content product B [g/100g protein]

and

amino acid (x) iAUC0-240 product A [µmol/L*min] / amino acid (x) iAUC0-240 product B [µmol/L*min]

where amino acid (x) = leucine, isoleucine, valine, histidine, lysine, methionine, phenylalanine, threonine, tryptophan, alanine, arginine, asparagine, aspartic acid, glutamic acid, glutamine, glycine, serine, tyrosine, cysteine or proline

Sub-study Plantino II:

Relative content of amino acids in dietary protein and relative amount of amino acids appearing in the blood for the 4 hour period after the ingestion of product E, F or G versus product D:

amino acid (x) content product E [g/100g protein] / amino acid (x) content product D [g/100g protein]
and
amino acid (x) iAUC0-240 product E [µmol/L*min] / amino acid (x) iAUC0-240 product D [µmol/L*min]

amino acid (x) content product F [g/100g protein] / amino acid (x) content product D [g/100g protein]
and
amino acid (x) iAUC0-240 product F [µmol/L*min] / amino acid (x) iAUC0-240 product D [µmol/L*min]

amino acid (x) content product G [g/100g protein] / amino acid (x) content product D [g/100g protein]
and
amino acid (x) iAUC0-240 product G [µmol/L*min] / amino acid (x) iAUC0-240 product D [µmol/L*min]

where amino acid (x) = leucine, isoleucine, valine, histidine, lysine, methionine, phenylalanine, threonine, tryptophan, alanine, arginine,

asparagine, aspartic acid, glutamic acid, glutamine, glycine, serine, tyrosine, cysteine or proline

- Postprandial serum concentrations of individual amino acids leucine, isoleucine, valine, histidine, lysine, methionine, phenylalanine, threonine, tryptophan, alanine, arginine, asparagine, aspartic acid, glutamic acid, glutamine, glycine, serine, tyrosine, cysteine and proline over time and for each amino acid:
o iAUC0-240 [µmol/L*min]
o iCmax [µmol/L]
o Tmax [1]

- In Sub-study Plantino I: Relative content of amino acids in dietary protein and relative amount of amino acids appearing in the blood expressed as iCmax after the ingestion of product A or B versus product C or D and for product A vs product B:

amino acid (x) content product A [g/100g protein] / amino acid (x) content product C [g/100g protein]
and
amino acid (x) iCmax product A [µmol/L] / amino acid (x) iCmax product C [µmol/L]

and similar for product A versus product D, product B versus product C, product B versus product D and product A versus product B

where amino acid (x) = leucine, isoleucine, valine, histidine, lysine, methionine, phenylalanine, threonine, tryptophan, alanine, arginine, asparagine, aspartic acid, glutamic acid, glutamine, glycine, serine, tyrosine, cysteine or proline

- In Sub-study Plantino II: Relative content of amino acids in dietary protein and relative amount of amino acids appearing in the blood expressed as iCmax after the ingestion of product E, F or G versus product D:

amino acid (x) content product E [g/100g protein] / amino acid (x) content product D [g/100g protein]
and
amino acid (x) iCmax product E [µmol/L] / amino acid (x) iCmax product D [µmol/L]

and similar for product F versus product D and product G versus product D

where amino acid (x) = leucine, isoleucine, valine, histidine, lysine, methionine, phenylalanine, threonine, tryptophan, alanine, arginine, asparagine, aspartic acid, glutamic acid, glutamine, glycine, serine, tyrosine,

cysteine or proline

Secondary outcome

Demographics and subject characteristics

Parameters for describing demographics and subject characteristics in this

study are:

- Sex [male/female]

- Age [years]

Anthropometry

- Body weight [kg]

- Height [m]

- Calculated BMI [kg/m2]

Relevant medical history

Relevant prior and concomitant medication, nutritional supplements and medical

interventions

- Relevant prior and concomitant medication

- Prior and concomitant nutritional supplements

- Medical interventions

Product compliance

- Time for study product intake: start time study product intake [hour:minutes]

and end time study product intake [hour:minutes]

- Non-compliance with product intake: less than 100% of the product

Protocol compliance

- Adherence to instructions and restrictions

Study description

Background summary

The use of plant-based proteins in the daily diet is increasing and the demand for plant-based variants is also increasing for medical nutrition products. plant-based proteins have a different amino acid composition than proteins from animal sources, such as dairy protein. In the future, the use of plant-based proteins in medical nutrition can (partially) replace the use of dairy proteins, resulting in a lower burden on the environment.

Study objective

The aim of this research is to find out more about the speed at which different types of proteins are digested and absorbed into the blood. This is important because differences in the rate of digestion and absorption can affect the nutritional status of patients requiring medical nutrition.

Study design

This is a randomised controlled, double blind, crossover, single-centre exploratory study.

In order to limit the number of study visits and thereby the burden for each subject as well as to limit the number of product comparisons, the study will be conducted as two consecutive sub-studies with exactly the same set-up (sub-study Plantino I and Plantino II).

Intervention

Test products:
Sub-study Plantino I: 4 protein solutions: 2 x 100% dairy protein and 2x combination of dairy protein and plant-based protein
Sub-study Plantino II study: 4 protein solutions: 1 x 100% dairy protein and 3x 100% plant-based protein

Study burden and risks

The following description will be performed for sub-study Plantino I and II.

After a screening visit, subjects must take a study product, a total of 4 times during 4 study visits. During a study visit, 1 product is taken each time.
Blood will be drawn at 14 times during 4.5 hours. A follow-up call appointment will take place a few days after the last study visit.
During participation, subjects must adhere to a number of rules related to medication use and lifestyle. The study is conducted with healthy adults and subjects take a single food product at each study visit that is expected to cause no discomfort to the subject. The risks of the other study activities are very limited; there is a small risk of pain/discomfort during the blood draw.
The burden of this study on subjects is considered to be low and the benefits of gaining more knowledge about the properties of the food products outweigh the low burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >= 18 and <= 70 years
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 gastrointestinal (GI) disease or surgery that may interfere with GI function and/or protein metabolism, including but not limited to phenylketonuria, pancreatitis, short bowel syndrome, celiac disease, Crohn*s disease, 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, opioid analgesics, anticoagulants, corticosteroids, laxatives, growth hormone, testosterone, immunosuppressants, or insulin).
4. Allergy to soy, pea and/or cow*s milk protein
5. Adherence to a weight loss program
6. Current eating disorder, e.g. anorexia nervosa or bulimia
7. Known pregnancy and/or lactation
8. Current smoking or stopped smoking for < 1 month prior to screening (except for incidental smoking of <= 3 cigarettes/cigars/pipes per week on average in the last month prior to screening)
9. 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)
10. Drug or medicine abuse in opinion of the investigator
11. Any known bleeding disorder
12. Known difficulties with placement of and/or blood drawings from a cannula
13. Active participation in any other study with investigational or marketed products concomitantly or within 4 weeks prior to screening
14. Major medical or major surgical event requiring hospitalization within the preceding 3 months and/or scheduled in the period of study participation
15. Investigator*s uncertainty about the willingness or ability of the subject

to comply with the protocol requirements
16. Employees of Nutricia Research and/or their family members or relatives

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-03-2023
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	13-02-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-08-2023
Application type:	Amendment

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	NL82913.056.22