# The acute postprandial response of blood amino acids in older adults after consumption of dairy protein, plant protein and their blend

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50244

**Source**
ToetsingOnline

**Brief title**
Postprandial Amino acid Response - PAR-study

### Condition

- Other condition
- Muscle disorders

**Synonym**
sacropenia; age-related muscle mass loss

**Health condition**

sarcopenie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Ingredia SA
**Source(s) of monetary or material Support:** bedrijven

## Intervention

**Keyword:** aminoacid kinetics, dietary protein, elderly, protein quality

## Outcome measures

### Primary outcome

Postprandial blood amino acid response, up to 5 hours after consumption of a

protein drink measured (incremental area under curve, Cmax and Tmax).

### Secondary outcome

Postprandial insulin response

potential muscle effect as assessed by an vitro muscle assay

# Study description

### Background summary

Increasing muscle protein synthesis via protein-based nutrition, with or without exercise, maintains a strong, healthy muscle mass, which in turn leads to improved health, independence and functionality in older adults. There is increased interest in plant-based proteins, but these have in general a lower anabolic effect than animal proteins. Various strategies have been suggested to augment the anabolic properties of plant proteins, including using plant-animal protein blends. However, only little is known yet about the anabolic properties of such an approach. As the peripheral metabolic availability of proteins is an important aspect that has to be taken into account when screening the anabolic properties of protein sources/blends, it is the aim of this study to investigate the postprandial AA response of milk protein, micellar casein, pea protein, and a milk protein-pea protein blend in healthy older adults.

### Study objective

The primary objective is to quantify the postprandial area under the curve (iAUC), the maximal level (Cmax) and the time profile (Tmax) of blood amino acids after ingestion of milk protein, micellar casein, pea protein, and a milk protein-pea protein blend in healthy older adults.
Secondary objectives are to quantify the postprandial insulin response, and to quantify the potential muscular response, using an ex vivo muscle cell assay, of postprandial blood derived from healthy older adults after ingestion of milk protein, micellar casein, pea protein, and a milk protein-pea protein blend

### Study design

The study is designed as a randomized, single-blinded within-subject (cross-over) trial in which a group of 12 subjects receive 4 different protein drinks.

### Intervention

Four different protein drinks will be investigated: milk protein, micellar casein, pea protein, and a milk protein/ pea protein blend. All drinks will contain a 20 gram protein load. All protein supplements will be mixed with 250 mL water and contain some additional non-caloric flavorings

### Study burden and risks

This study is related to older adults, as maintenance of muscle mass and function * via protein based nutrition - is important in an ageing population. Research participants will not directly benefit from their participation. The risks associated with participation in this study are the development of bruises due to cannulation and transiently decreased iron status due to repeated blood sampling. The total amount of blood sampled during the 4 week period is 480 ml (120 ml per week). Compared to the 500 ml which is collected at a single occasion during blood donation, this amount is not expected to result in side effects such as fatigue. The main burden of this study consists of the time involved (4 days ~ 6 hours), and the blood collection.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Elderly (65 years and older)

## Inclusion criteria

* Age *65 and *80
* BMI *20 and *32 kg/m2
* Non-smoking
* Healthy as assessed by a lifestyle and health questionnaire (*Verklaring leefgewoonten en gezondheid*) and according to the judgment of the study physician.

## Exclusion criteria

* Having a history of medical or surgical events that may significantly affect the study outcome
* 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 (> 6.7 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

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-10-2021 |
| Enrollment: | 12 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 22-09-2021 |
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |

# 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 |
| --- | --- |
| ClinicalTrials.gov | NCT04935788 |
| CCMO | NL78067.028.21 |

# Study results

Date completed: 22-11-2021

Actual enrolment: 12

**Summary results**

Trial is onging in other countries