Effects of Adding Appetite Stimulants to a Fibre Containing High-Protein ONS on Appetite-Related Outcomes in Older Adults

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

Summary

ID

NL-OMON57067

Source
ToetsingOnline

Brief title
APPOLO 2

Condition

- Other condition

Synonym
not applicable

Health condition

Geen, het betreft oudere volwassen zonder specifieke aandoening

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

Keyword: Adults, Appetite, Oral Nutritional Support (ONS), Satiety

Outcome measures

Primary outcome

The main outcome parameter in this study is the composite satiety score (CSS) measured from baseline until 120 minutes after starting the consumption of the study product.

The CSS will be calculated through the equation (satiety + fullness + (100 - hunger) + (100 - prospective food consumption))/ 4. Satiety, fullness, hunger and prospective food consumption will be assessed on a VAS. The CSS ranges from 0 to 100.

Secondary outcome

Other outcome parameters in this study are:

Composite satiety score (CSS) from baseline until 120 minutes after starting the consumption of the study product:

- Absolute values [score] at baseline (-5 minutes) and 15, 30, 45, 60, 90 and 120 minutes after starting the consumption of the study product.
- Change from baseline [score] at 15, 30, 45, 60, 90 and 120 minutes after starting the consumption of the study product.

- Satiety, fullness, hunger, prospective food consumption measured from baseline until 120 minutes after starting the consumption of the study product.:

- AUC [score x minutes].

- Absolute values [score] at baseline (-5 minutes) and 15, 30, 45, 60, 90 and 120 minutes after starting the consumption of the study product.

- Change from baseline [score] at 15, 30, 45, 60, 90 and 120 minutes after starting the consumption of the study product.

- Adherence to use of the study product, defined as volume consumed within 10 minutes relative to 1 serving [%].

- Compliance to use of the study product, defined as volume consumed within 10 minutes relative to 1 serving [%]

- Overall liking of the study product, assessed 10 minutes after starting the consumption of the study product on a liking scale ranging from 1 to 10.

Study description

Background summary

Malnutrition is a widespread problem affecting the lives of millions of people each year. It is most commonly found in association with disease and can affect all age groups, from older adults to young children. It is more common in older people as they often have several co-morbidities. Oral nutritional supplements (ONS) have proven clinical benefits for malnourished patients since its use is linked to lower mortality and lower complication rates when compared to standard care.

Good adherence to ONS prescription is crucial to achieve the goals that are aimed for. A lack of appetite and increased feeling of fullness in older adults are being recognized as important barriers to consuming a bottle of ONS and thereby adherence.

Anorexia of aging is a reduced appetite and/or food intake in old age. One of the underlying mechanisms for this involves changes in gastrointestinal motility, resulting in early/postprandial satiety. Test product L-arginine en L-glutamate can promote gastric emptying and relaxation of the stomach and therefore reduces the increased feeling of fullness.

Study objective

During the study, the effects of the test product in ONS are examined:
* Test product l-Arginine and l-Glutamate as separate amino acids that are combined

This study examines the effects of adding the test product in ONS when compared to the ONS alone.
It is also investigated whether extra fibres in ONS have an effect on the feeling of satiety and appetite of subjects.

Study design

This is a randomized, controlled, single blind, monocentric, crossover study.

Given the large inter-individual variability in eating behavior and perceptions of subjective appetite, a cross-over design is chosen for this study. This design is particularly suitable for comparing the Test Product and Control Product, which is the primary objective of this study.

Intervention

he subjects are randomized to 1 of the 4 study arms on the basis of a randomization list.
In each study arm, participants receive 1 amount of a sip feed during the 4 visit days.

The sip feeds consumed are:
* Testproduct: ONS Compact Protein + amino acids L-Arginine en L-Glutamate
* Control product: ONS Compact Protein
* Control product: ONS Compact Fibre + added proteins
* Control product: ONS Compact Fibre + amino acids L-Arginine en L-Glutamate + added proteins

Every participant consumes the same sip feeds. Only in a different sequence according to the designated order in the randomization list.

Study burden and risks

The burden on the participants is minimal. The older adults have no specific

condition or indication and the study participation is voluntary.
The expected risks associated with the study product are minimal. The participants are asked to visit the site 4x to consume the ONS with or without the test product and to complete subject questionnaires at fixed time points for +/- 2.5 hours per study visit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

1. 65 years of age or older
2. Able to consume high energy and/or high protein ONS at discretion of the Investigator
3. Written informed consent
4. Willing and able to refrain from smoking during the visits
5. Able to speak and read in Dutch to communicate with the site staff and

comply with the instructions and requirements of the study.

Exclusion criteria

1. Any known condition that interferes with the gastric emptying (e.g., gastroparesis, gastric stoma, hypothyroidism, hyperthyroidism, multiple sclerosis, Parkinson disease).
2. Any known metabolic condition that interferes with the breakdown of amino acids (e.g. arginase deficiency, urea cycle disorder)
3. Known history of gastric surgery e.g. (partial) gastrectomy or any other procedure for stomach volume reduction, including gastric banding, gastric balloon.
4. Known chronic/continuous use, and/or within 24-48h before the visit, of medication that strongly affects with gastric emptying or gastric acid secretion (e.g., metoclopramide, opioid analgesics, calcium channel blockers, Beta-Adrenergic Receptor Agonists, H2 receptor antagonists, proton pump inhibitors; tricyclic antidepressants such as amitriptyline, imipramine, systemic steroids)
5. Known active cancer treatment 4 weeks prior the study start
6. Body Mass Index >= 30.0 kg/m²
7. Presence of Diabetes Mellitus (self-reported or the use of Diabetes medication: i.e., insulin, biguanides, DPP-4 inhibitors, GLP-1 receptor agonists)
8. Investigator*s uncertainty about the willingness or ability of the subject to comply with the protocol requirements, for example due to the presence of a psychiatric disorder (e.g. major depression, psychoses), dementia or Alzheimer*s disease
9. Known renal dysfunction with protein restriction diet
10. Known allergy to cow*s milk protein
11. Known allergy to soy
12. Known galactosaemia
13. Known lactose intolerance
14. Excessive alcohol consumption (use of > 14 units per week for women or > 21 units per week for men, on average during the past 6 months).
15. Drug abuse based on investigator*s judgement.
16. Any contraindication to oral feeding per se being: any degree of dysphagia, gastrointestinal failure or suppressed gastrointestinal function, complete intestinal obstruction and major intra-abdominal sepsis.
17. Enrolment in any other studies involving investigational or marketed products concomitantly or within two weeks prior to baseline
18. Employees, family members or other relatives of employees of the participating centre or of Danone Global Research & Innovation Center.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2024
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2024
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
ClinicalTrials.gov	NCT06645184
CCMO	NL87151.056.24