An exploratory study investigating the effect of adding an appetite stimulant to an ONS on appetite-related outcomes in nursing home residents and in older adults in need of additional nutritional support

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The main objective of this study is to explore the acute effects of adding an appetite stimulant to an ONS on the composite satiety score (CSS, a combined score of satiety, fullness, hunger and prospective food consumption) compared with an ONS...

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

Summary

ID

NL-OMON52167

Source
ToetsingOnline

Brief title
Appetite study in nursing homes and older adults needing nutrition

Condition

- Other condition

Synonym
fullness, satiety

Health condition

geen aandoening, doelgroep is kwetsbare ouderen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: appetite, 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:

- Area under the curve (AUC; score x minutes)

- Incremental area under the curve (iAUC; 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

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, with scores ranging from 0 to 100. The CSS also ranges from 0 to 100.

Secondary outcome

Other outcome parameters in this study are:

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

- AUC (score x minutes)
- iAUC (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 15 minutes relative to 1 serving (%)

Overall liking of the study product (score), assessed 15 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. Oral nutritional supplements (ONS) have proven clinical benefits for malnourished patients: ONS 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 ageing is a reduced appetite and/or food intake in old age. One of the underlying mechanisms for this relates to gastrointestinal motility changes, resulting in early/postprandial satiety. Product AS-2, an appetite stimulant, promotes gastric emptying and relaxation of the stomach and thereby reduces the increased feeling of fullness.

This study is an exploratory study investigating the effect of a new product concept, an ONS with the addition of an appetite stimulant (AS-2), on appetite-related outcomes in nursing home residents and in older adults in need of additional nutritional support.

The hypothesis formulation for the primary outcome parameter is:
H0: The effect of using the test product is equal to the effect of using control product with respect to the CSS (Composite Satiety Score) in nursing home residents and in older adults in need of additional nutritional support.
H1: The effect of using the test product is unequal to the effect of using control product with respect to the CSS in nursing home residents and in older adults in need of additional nutritional support

Study objective

The main objective of this study is to explore the acute effects of adding an appetite stimulant to an ONS on the composite satiety score (CSS, a combined score of satiety, fullness, hunger and prospective food consumption) compared with an ONS without this appetite stimulant in nursing home residents and in older adults in need of additional nutritional support. The CSS will be assessed from baseline until 120 minutes after starting the consumption of the study product.

The other objectives of this study are to explore the effects of adding an appetite stimulant to an ONS compared with an ONS without this appetite stimulant in nursing home residents and in older adults in need of additional nutritional support, on the following outcome parameters:
- Satiety
- Fullness
- Hunger
- Prospective food consumption
- Adherence (defined as volume consumed within 15 minutes relative to 1 serving)
- Overall liking

Study design

A randomised, controlled, single-blind, multi-centre cross-over study

Intervention

All subjects will consume both study products (the test product and control product) on two separate test days (Visit 1 and Visit 3). Subjects will be randomly allocated to receive either the test product or the control product at the first test day. Subjects will receive the other product at the second testday.

Study burden and risks

There are no Adverse Events expected associated with participation
Subjects are not expected to benefit from participation
Participation in the study means an investment of time by the subject for a screening visit, 2 test days and 2 follow-up appointments.
The subjects regularly complete questionnaires during participation.
The subjects are asked to follow some instructions regarding food, drink and activity level on test days.

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. Residing in a nursing home
OR
If not residing in a nursing home, in need of additional nutritional support: defined as currently prescribed with oral nutritional supplements (ONS) or being identified as malnourished/at risk of malnutrition based on the MNA-SF.
3. Able to consume high energy and/or high protein ONS at discretion of the Investigator
4. Written informed consent

Exclusion criteria

1. Any known gastrointestinal (GI) disease that interferes with the GI motility and nutritional intake, e.g. constipation or diarrhoea secondary to neuropathy, diarrhoea due to chronic inflammatory bowel disease, gastroparesis
2. Any known metabolic condition that interferes with the breakdown of amino acids (e.g. arginase deficiency, urea cycle disorder)
3. Known history of GI surgery (except appendectomy) that interferes with the GI function, e.g. ileostomy, colostomy, (partial) gastrectomy or any other procedure for stomach volume reduction, including gastric banding
4. Investigator*s uncertainty about the willingness or ability of the subject to comply with the protocol requirements, e.g. due to the presence of a psychiatric disorder (e.g. major depression, psychoses), dementia or Alzheimer*s disease
5. Known renal dysfunction (e.g. estimated Glomerular Filtration Rate <30 mL/min/1.73 m2)
6. Known allergy to cow*s milk protein
7. Known galactosaemia
8. Known severe lactose intolerance without using lactase
9. Enrolment in any other studies involving investigational or marketed products concomitantly within two weeks prior to baseline

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:	Recruitment stopped
Start date (anticipated):	19-10-2021
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-11-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-04-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22468
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Netherlands Trial Register: Trial NL9612
CCMO	NL77775.100.21
OMON	NL-OMON22468