A study to investigate appetite in older adults residing in nursing homes.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22468

Source
Nationaal Trial Register

Brief title
APPOLO

Health condition

NA

Sponsors and support

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

Intervention

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

This is a randomised, controlled, single-blind, multi-centre, cross-over study to explore the effects of adding an appetite stimulant to an ONS compared with an ONS without this appetite stimulant in nursing home residents on appetite-related outcomes.

Study objective

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
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

Study design

V0 (screening); V1 (first test day within 10 days after visit 0); V2 (22-48 hours after V1) V3 (second test day 2-14 days after first test day), V4 (22-48 hours after V3)

Intervention

Duration of intervention: 2 weeks
Intervention group: One bottle of ONS (125 mL), mixed with an appetite stimulant dissolved in 5 mL of water
Control group: One bottle of ONS (125 mL) mixed with 5 mL of water

Contacts

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Eligibility criteria

Inclusion criteria

1. 65 years of age or older
2. Residing in a nursing home
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 gastrointestinal 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
3. 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, for example due to the presence of a psychiatric disorder (e.g. major

depression, psychoses), dementia or Alzheimer’s disease
5. Known allergy to cow’s milk protein
6. Known galactosaemia
7. Known severe lactose intolerance without using lactase
8. Enrolment in any other studies involving investigational or marketed products concomitantly or within two weeks prior to baseline

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	45
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
NA

Ethics review

Positive opinion

Date:	15-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52167
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9612
CCMO	NL77775.100.21
OMON	NL-OMON52167

Study results