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

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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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22468

Bron
Nationaal Trial Register

Verkorte titel
APPOLO

Aandoening

NA

Ondersteuning

Primaire sponsor: Danone Nutricia Research
Overige ondersteuning: Danone Nutricia Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
NA

Ethische beoordeling

Positief advies

Datum:	15-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52167
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten