

Randomised controlled trial to evaluate tolerance, intake and safety of a new high-energy high-protein oral nutritional supplement in elderly subjects in need of oral nutritional support.

Gepubliceerd: 12-10-2010 Laatste bijgewerkt: 18-08-2022

Tolerance to new high-energy high-protein oral nutritional supplement is equal to standard high-energy high-protein oral nutritional supplement.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26236

Bron

Nationaal Trial Register

Verkorte titel

Compass

Aandoening

Malnutrition

Ondervoeding

Ondersteuning

Primaire sponsor: Danone Research - Centre for Specialised Nutrition

Overige ondersteuning: Danone Research - Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tolerance:

1. Daily stool frequency and consistency;

2. Incidence and intensity of gastrointestinal symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial a new high-energy high-protein oral nutritional supplement will be compared with standard high-energy high-protein oral nutritional supplement on tolerance in elderly subjects in need of oral nutritional support.

Doel van het onderzoek

Tolerance to new high-energy high-protein oral nutritional supplement is equal to standard high-energy high-protein oral nutritional supplement.

Onderzoeksopzet

Screening, Baseline, week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8, Follow-up.

Onderzoeksproduct en/of interventie

Duration of intervention: 56 days.

1. Intervention group: New high-energy high-protein oral nutritional supplement;
2. Control group: Standard high-energy high-protein oral nutritional supplement.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male/female subjects $\geq$ 65 years of age;
2. Subject is in need of oral nutritional support of $\geq$ 300 kcal/day;
3. Subject is expected to require oral nutritional support for at least 8 weeks;
4. Subject has given written informed consent;
5. Subject is able to comply with the protocol (e.g. answer questions, collect urine).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known inflammatory bowel disease (e.g. Crohn's disease);
2. Known lactose intolerance and not using lactase;
3. Known galactosaemia;
4. Known cow's milk allergy;

5. Known major hepatic dysfunction: symptomatic hepatic dysfunction or previous serum transaminase (ALAT, ASAT, or alkaline phosphatase) levels more than 5 times upper limit of normal;
6. Known renal dysfunction: symptomatic renal dysfunction or a previous GFR < 60 mL/min/1.73 m² for longer than 3 months (stage 3 - stage 5 chronic kidney disease);
7. Requirement of a protein restricted diet (such as for renal failure);
8. Ileostomy or colostomy;
9. Parenteral feeding;
10. Tube feeding;
11. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;
12. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	14-10-2010
Aantal proefpersonen:	68
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 12-10-2010

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2449
NTR-old	NTR2565
Ander register	Danone Research : Sip.4.C/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A