

Randomised controlled trial to evaluate tolerance of a new high energy product with vitamins, minerals and protein in subjects in need of high caloric oral nutritional support.

Gepubliceerd: 31-05-2011 Laatste bijgewerkt: 18-08-2022

Tolerance to new high energy product with vitamins, minerals and protein is equal to standard high energy product.

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

Samenvatting

ID

NL-OMON23160

Bron

NTR

Verkorte titel

CALEX

Aandoening

Malnutrition

Ondervoeding

Ondersteuning

Primaire sponsor: Danone Research "C Centre for Specialised Nutrition

Overige ondersteuning: Danone Research "C Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tolerance:

1. Daily stool frequency and consistency;

2. Occurrence and intensity of gastrointestinal symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial a new high energy product with vitamins, minerals and protein will be compared with standard high energy product on tolerance in subjects in need of high caloric oral nutritional support.

Doel van het onderzoek

Tolerance to new high energy product with vitamins, minerals and protein is equal to standard high energy product.

Onderzoeksopzet

Screening, Baseline, week 1, week 2, week 3, week 4, Follow Up.

Onderzoeksproduct en/of interventie

Duration of intervention: 28 days.

1. Intervention group: New high energy product with vitamins, minerals and protein;
2. Control group: Standard high energy product.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subjects (male/female) $\geq$ 18 years of age at the start of the Baseline period;
2. Subject is prescribed high caloric oral nutritional support (subject can be current or new user);
3. In case of new users: MUST (Malnutrition Universal Screening Tool) score 1 (medium risk of malnutrition), or 2 or more (high risk of malnutrition);
4. Subject is expected to require high caloric oral nutritional support for at least 4 weeks;
5. Subject has given written informed consent;
6. Subject is able to comply with the protocol (e.g. answer questions).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known inflammatory bowel disease (e.g. Crohn's disease);
2. Pancreatitis or illness with known fat malabsorption;
3. Exposure to chemotherapy concomitantly or within two weeks prior to entry into the study;

4. Life expectancy of ≤ 3 months;
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 major renal dysfunction: symptomatic renal dysfunction, previous serum creatinine level more than 1.8 times upper limit of normal, or requiring dialysis;
7. Ileostomy or colostomy;
8. Known galactosaemia;
9. Know cow's milk allergy;
10. Parenteral feeding;
11. Tube feeding;
12. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;
13. Participation in any other study 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:	01-07-2011
Aantal proefpersonen:	50

Type:

Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:

31-05-2011

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
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NTR-new	NL2783
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NTR-old	NTR2923
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Ander register Danone Research "C Centre for Specialised Nutrition : Cal.1.C/A

ISRCTN	ISRCTN wordt niet meer aangevraagd.
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Resultaten

Samenvatting resultaten

N/A