Randomised controlled trial to evaluate tolerance of a new fibre-enriched sip feed in subjects in need of oral nutritional support.

Gepubliceerd: 17-11-2009 Laatst bijgewerkt: 18-08-2022

Tolerance to new fibre-enriched sip feed is equal to standard fibre-enriched sip feed.

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

Samenvatting

ID

NL-OMON26327

Bron
NTR

Verkorte titel
CF trial

Aandoening

Malnutrition

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, daily:
1. Stool frequency;
2. Incidence of liquid stools;
3. Incidence and intensity gastrointestinal symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial a new fibre-enriched sip feed will be compared with standard fibre-enriched sip feed on tolerance in subjects in need of nutritional support.

Doel van het onderzoek

Tolerance to new fibre-enriched sip feed is equal to standard fibre-enriched sip feed.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Duration of intervention: 28 days;

Intervention group: new fibre-enriched sip feed;

Control group: standard fibre-enriched sip feed.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subjects (male/female) ≥ 50 years of age at the start of the Baseline period;

2. Subject is prescribed oral nutritional support of 300 kcal/day of sip feed (subject can be current or new user);

3. In case of new users: MUST score 1 (medium risk of malnutrition), or 2 or more (high risk of malnutrition);

4. Subject is expected to require 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 diseases (e.g. Crohn’s disease);

2. Known lactose intolerance and not using lactase;

3. Known galactosemia;

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 major renal dysfunction: symptomatic renal dysfunction, previous serum creatinine level more than 1.8 times upper limit of normal, or requiring dialysis;

7. Subject with an ileostomy or colostomy;

8. Parenteral feeding;

9. Tube feeding;

10. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;

11. 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
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2009
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-11-2009
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	NL1996
NTR-old	NTR2113
Ander register	Danone Research – Centre for Specialised Nutrition : Sip.7.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A