Trial to evaluate tolerance and safety of a new pre-thickened sip feed in subjects in need of oral nutritional support.

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It is expected that the new pre-thickened sip feed is as safe as and well-tolerated as standard sip feed thickened with a commercially available thickener.

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

Samenvatting

ID

NL-OMON21624

Bron
NTR

Verkorte titel
TOAD (Tolerance Of A Dysphagia pre-thickened sip feed)

Aandoening

-malnutrition
-dysphagia

Ondersteuning

Primaire sponsor: Danone Research B.V.
Overige ondersteuning: Danone Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Stool frequency;
2. Incidence and intensity of gastrointestinal symptoms;
3. Safety parameters in blood.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study tolerance and safety of a pre-thickened sip feed will be compared to a standard sip feed, thickened with a commercially available thickener in subjects in need of oral nutritional support. Subjects will be using the product for 4 weeks.

Doel van het onderzoek

It is expected that the new pre-thickened sip feed is as safe as and well-tolerated as standard sip feed thickened with a commercially available thickener.

Onderzoeksopzet

1. Visit 1: screening;

2. Visit 2: baseline (day 0);

3. Visit 3: day 14;

4. Visit 4: day 28 (end of intervention);

5. Follow-up visit or phone call after 3 days.

Onderzoeksproduct en/of interventie

After randomisation, patients will receive either the pre-thickened sip feed or a standard sip feed thickened with a commercially available thickening powder for 28 days. Measurements of weight, stool frequency, GI symptoms, food & fluid intake, and product appreciation during the study period using stool records, GI questionnaires, dietary records and product appreciation questionnaires. Blood samples will be taken and analysed at Baseline, Day 14, and Day 28.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male or female adult at least 18 years of age;

2. Subject is prescribed oral nutritional support of at least 300 kcal/day of energy enriched sip feed;

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

4. Subject requires oral nutritional support for at least 4 weeks;

5. Written informed consent from subject.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known inflammatory bowel diseases (e.g. Crohns disease);

2. Known lactose intolerance and not using lactase;

3. Known galactosemia;

4. Major hepatic or renal dysfunction;

5. Subject with an ileostomy or colostomy;

6. Strong dislike of the flavours to be tested;

7. Requirement for oral nutritional support other than (thickened) energy enriched sip feeds (e.g. high protein sip feeds, disease specific sip feeds);

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

9. 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:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-01-2009
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	NL1563
NTR-old	NTR1643
Ander register	sponsor : Sip.5.c/a
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A