

Randomised, controlled, open label, cross-over trial to evaluate the tolerance of a new paediatric sip feed in children in need of oral nutritional support.

Gepubliceerd: 27-05-2010 Laatste bijgewerkt: 18-08-2022

Tolerance of the new paediatric sip feed is equal to the standard paediatric sip feed.

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

Samenvatting

ID

NL-OMON26666

Bron

Nationaal Trial Register

Verkorte titel

PAT-trial

Aandoening

Children in need of oral nutritional support

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 stool frequency (with diary) and frequency and intensity of gastro-intestinal symptoms (with questionnaire).

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial the tolerance, appreciation and compliance of a new fibre-enriched paediatric sip feed will be compared with a standard fibre-enriched paediatric sip feed in children in need of oral nutritional support.

Doel van het onderzoek

Tolerance of the new paediatric sip feed is equal to the standard paediatric sip feed.

Onderzoeksopzet

1. Visit 1 Baseline (Day 0);
2. Visit 2 (Day 21);
3. Visit 3 (Day 42);
4. Follow-up.

Onderzoeksproduct en/of interventie

Test-product: A new paediatric sip feed that is nutritionally complete and energy dense (1.5 kcal/ml). Amount: As pre-scribed by Health Care Professional.

Control-product: A standard fibre-enriched paediatric sip-feed that is already on the market. Amount: As pre-scribed by Health Care Professional.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male and female subjects, aged 3-12 years (including 3 and 12 years) in need of oral nutritional support (subject can be current or new paediatric sip feed user);
2. Subject requires a paediatric sip feed for at least 6 weeks;
3. Both hospitalized subjects and out-patients;
4. Stable health status and expected to remain stable throughout the study (in the opinion of the Health Care Professional);
5. Written informed consent from parents/guardian and subject (if applicable according to local law).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cow's milk allergy, known inflammatory bowel diseases, bowel resection;
2. Subjects requiring a fibre-free diet;
3. Known allergy for fruit (apple, pear, strawberry, raspberry, banana, apricot, lemon) and/or carrot;
4. Subjects requiring an adult rather than a paediatric sip feed;

5. Major renal dysfunction (if requiring, but not yet receiving, dialysis);
6. Major hepatic dysfunction (e.g. hepatitis, congenital abnormalities affecting the liver);
7. Major gastrointestinal intolerance (e.g. vomiting, diarrhoea);
8. Inherited metabolic disorders, including galactosaemia;
9. Use of parenteral feeding and/or enteral tube-feeding;
10. Investigator's uncertainty about the willingness or ability of the child/carer to comply with the protocol requirements;
11. 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:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	18-05-2010
Aantal proefpersonen:	28
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	27-05-2010

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	NL2215
NTR-old	NTR2340
Ander register	Danone Research – Centre for Specialised Nutrition : Ped.1.C/J
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A