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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26666

Source
NTR

Brief title
PAT-trial

Health condition

Children in need of oral nutritional support

Sponsors and support

Primary sponsor: Danone Research – Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research – Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Product appreciation: Overall liking and product evaluation carer (both with questionnaire);

2. Daily study product intake (with diary).

Study description

Background summary

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.

Study objective

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

Study design

1. Visit 1 Baseline (Day 0);

2. Visit 2 (Day 21);

3. Visit 3 (Day 42);

4. Follow-up.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-05-2010
Enrollment:	28
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-05-2010

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A