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

No registrations found.

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

Summary

ID

NL-OMON26327

Source
NTR

Brief title
CF trial

Health condition

Malnutrition

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:

1. Stool frequency;

2. Incidence of liquid stools;

3. Incidence and intensity gastrointestinal symptoms.

Secondary outcome

1. Study product intake;

2. Product appreciation.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

Duration of intervention: 28 days;

Intervention group: new fibre-enriched sip feed;

Control group: standard fibre-enriched sip feed.

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A