Randomised controlled trial to evaluate tolerance of a new high energy product with vitamins, minerals and protein in subjects in need of high caloric oral nutritional support.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23160

Source
NTR

Brief title
CALEX

Health condition

Malnutrition
Ondervoeding

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Tolerance:

1. Daily stool frequency and consistency;

2. Occurrence and intensity of gastrointestinal symptoms.

Secondary outcome

Product appreciation: Product appreciation questionnaire.

Study description

Background summary

In this trial a new high energy product with vitamins, minerals and protein will be compared with standard high energy product on tolerance in subjects in need of high caloric oral nutritional support.

Study objective

Tolerance to new high energy product with vitamins, minerals and protein is equal to standard high energy product.

Study design

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

Intervention

Duration of intervention: 28 days.

1. Intervention group: New high energy product with vitamins, minerals and protein;

2. Control group: Standard high energy product.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subjects (male/female) ≥ 18 years of age at the start of the Baseline period;

2. Subject is prescribed high caloric oral nutritional support (subject can be current or new user);

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

4. Subject is expected to require high caloric 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 disease (e.g. Crohn's disease);

2. Pancreatitis or illness with known fat malabsorption;

3. Exposure to chemotherapy concomitantly or within two weeks prior to entry into the study;

4. Life expectancy of ≤ 3 months;

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. Ileostomy or colostomy;

8. Known galactosaemia;

9. Know cow's milk allergy;

10. Parenteral feeding;

11. Tube feeding;

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

13. 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-07-2011
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion Date:	31-05-2011
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	NL2783
NTR-old	NTR2923
Other	Danone Research ¨C Centre for Specialised Nutrition : Cal.1.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A