Randomised controlled trial to evaluate tolerance, intake and safety of a new high-energy high-protein oral nutritional supplement in elderly subjects in need of oral nutritional support.

No registrations found.

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

Summary

ID

NL-OMON26236

Source
Nationaal Trial Register

Brief title
Compass

Health condition

Malnutrition
Ondervoeding

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:

1. Daily stool frequency and consistency;

2. Incidence and intensity of gastrointestinal symptoms.

Secondary outcome

Intake and safety.

Study description

Background summary

In this trial a new high-energy high-protein oral nutritional supplement will be compared with standard high-energy high-protein oral nutritional supplement on tolerance in elderly subjects in need of oral nutritional support.

Study objective

Tolerance to new high-energy high-protein oral nutritional supplement is equal to standard high-energy high-protein oral nutritional supplement.

Study design

Screening, Baseline, week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8, Follow-up.

Intervention

Duration of intervention: 56 days.

1. Intervention group: New high-energy high-protein oral nutritional supplement;

2. Control group: Standard high-energy high-protein oral nutritional supplement.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male/female subjects ≥ 65 years of age;

2. Subject is in need of oral nutritional support of ≥ 300 kcal/day;

3. Subject is expected to require oral nutritional support for at least 8 weeks;

4. Subject has given written informed consent;

5. Subject is able to comply with the protocol (e.g. answer questions, collect urine).

Exclusion criteria

1. Known inflammatory bowel disease (e.g. Crohn's disease);

2. Known lactose intolerance and not using lactase;

3. Known galactosaemia;

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 renal dysfunction: symptomatic renal dysfunction or a previous GFR < 60 mL/min/1.73 m2 for longer than 3 months (stage 3 - stage 5 chronic kidney disease);

7. Requirement of a protein restricted diet (such as for renal failure);

8. Ileostomy or colostomy;

9. Parenteral feeding;

10. Tube feeding;

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

12. 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:	Recruitment stopped
Start date (anticipated):	14-10-2010
Enrollment:	68
Type:	Actual

Ethics review

Positive opinion

Date:	12-10-2010
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	NL2449
NTR-old	NTR2565
Other	Danone Research : Sip.4.C/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A