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.

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The primary objective of this study is to evaluate tolerance of a new high-energy high-protein oral nutritional supplement compared to a commercially available high-energy high-protein oral nutritional supplement in elderly subjects in need of oral...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON36680

Source
ToetsingOnline

Brief title
Compass

Condition

- Appetite and general nutritional disorders

Synonym
malnutrition, poor nutritional status

Research involving
Human

Sponsors and support

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

Intervention

Keyword: high-protein, malnutrition, oral nutritional supplement

Outcome measures

Primary outcome

The primary parameter is tolerance. Tolerance will be evaluated by measuring

the following parameters:

- Daily stool frequency and consistency

- Tolerance questionnaire

Secondary outcome

The secundairy parameters are safety and intake. These will be evaluated by

measuring the following parameters:

- Daily study product intake

- Fluid intake

- Occurrence of (Serious) Adverse Events

- Blood parameters

- Urine parameters

- Paramters derived from blood and urine parameters

- Blood pressure

- Resting heart rate

Other parameters are:

- Body weight

- Body Mass Index

- Dietary Intake

- Product appreciation (for example taste).

Study description

Background summary

Many people of 65 years and older who suffer from unwanted weightloss are prescribed with oral nutritional supplement to supplement their normal food intake. Often they find it hard to completely consume the prescribed amount of oral nutritional supplement. Danone Research has developed a new high-energy high-protein oral nutritional supplement, specifically for people who can not or do not want to drink large volumes of oral nutritional supplement.

Study objective

The primary objective of this study is to evaluate tolerance of a new high-energy high-protein oral nutritional supplement compared to a commercially available high-energy high-protein oral nutritional supplement in elderly subjects in need of oral nutritional support.

The secondary objectives of this study are to evaluate intake and safety of a new high-energy high-protein oral nutritional supplement compared to a commercially available high-energy high-protein oral nutritional supplement in elderly subjects in need of oral nutritional support.

Study design

Randomised, controlled, single blind, parallel-group, multi-country study.

Intervention

One group receives daily at least 1 bottle of the new high-energy high-protein oral nutritional supplement, the other group receives daily at least 1 bottle of the standard high-energy high-protein oral nutritional supplement. The amount of bottles per day depends on what has been prescribed by the healthcare professional.

Study burden and risks

The burden for subjects is small and the expected risks are limited.

The burden for the subjects will be:
- Daily study product intake for 8 weeks
- 4 x completion of tolerance questionnaire
- 4 x completion of product appreciation questionnaire
- 3 x blood collection (with a chance for locale bleeding and/or pain due to the venapunction)
- 3 x urine collection
- 3 x measuring of the blood pressure
- 3 x measuring of the resting heart rate

The adverse events that might result from the new high-energy high-protein oral nutritional supplement are expected to be mild and acceptable for the study population. From the control product (the standard high-energy high-protein oral nutritional supplement) no adverse events are expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 phase:	2
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-01-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
CCMO	NL34478.072.10