Trial to evaluate tolerance and safety of a new pre-thickened sip feed in subjects in need of oral nutritional support.

No registrations found.

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

Summary

ID

NL-OMON21624

Source
NTR

Brief title
TOAD (Tolerance Of A Dysphagia pre-thickened sip feed)

Health condition

-malnutrition
-dysphagia

Sponsors and support

Primary sponsor: Danone Research B.V.
Source(s) of monetary or material Support: Danone Research B.V.

Intervention

Outcome measures

Primary outcome

1. Stool frequency;

2. Incidence and intensity of gastrointestinal symptoms;

3. Safety parameters in blood.

Secondary outcome

Study product intake (compliance).

Study description

Background summary

In this study tolerance and safety of a pre-thickened sip feed will be compared to a standard sip feed, thickened with a commercially available thickener in subjects in need of oral nutritional support. Subjects will be using the product for 4 weeks.

Study objective

It is expected that the new pre-thickened sip feed is as safe as and well-tolerated as standard sip feed thickened with a commercially available thickener.

Study design

1. Visit 1: screening;

2. Visit 2: baseline (day 0);

3. Visit 3: day 14;

4. Visit 4: day 28 (end of intervention);

5. Follow-up visit or phone call after 3 days.

Intervention

After randomisation, patients will receive either the pre-thickened sip feed or a standard sip feed thickened with a commercially available thickening powder for 28 days. Measurements of weight, stool frequency, GI symptoms, food & fluid intake, and product appreciation during the study period using stool records, GI questionnaires, dietary records and product appreciation questionnaires. Blood samples will be taken and analysed at Baseline, Day 14, and Day 28.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female adult at least 18 years of age;

2. Subject is prescribed oral nutritional support of at least 300 kcal/day of energy enriched sip feed;

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

4. Subject requires oral nutritional support for at least 4 weeks;

5. Written informed consent from subject.

Exclusion criteria

1. Known inflammatory bowel diseases (e.g. Crohns disease);

2. Known lactose intolerance and not using lactase;

3. Known galactosemia;

4. Major hepatic or renal dysfunction;

5. Subject with an ileostomy or colostomy;

6. Strong dislike of the flavours to be tested;

7. Requirement for oral nutritional support other than (thickened) energy enriched sip feeds (e.g. high protein sip feeds, disease specific sip feeds);

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

9. 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:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-01-2009
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	NL1563
NTR-old	NTR1643
Other	sponsor : Sip.5.c/a
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A