Evaluation of the gastro-intestinal tolerance, nutritional intake, and acceptability of an upgraded composition of an enteral tube feed for adults in need of long term nutritional support

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The objective of this study is to evaluate the gastro-intestinal tolerance, nutritional intake, and acceptability of an adjusted composition of an enteral tube feed for adults in need of long term nutritional support.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53226

Source
ToetsingOnline

Brief title
Peacock Butterfly

Condition

- Other condition

Synonym
in need of tube feed

Health condition

indicatie voor sondevoeding

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research

Intervention

Keyword: Gastro-intestinal tolerance, Nutritional intake, Product acceptability, Tube nutrition

Outcome measures

Primary outcome

Gastro-intestinal tolerance based on:

- stool pattern defined as: consistency and frequency (use of Bristol Stool

Form Scale)

- GI tolerance symptom questionnaire including symptoms as nausea, vomiting,

burping, constipation, diarrhea.

Secondary outcome

- Volume of tube feeding administration

- Product compliance

- Acceptability of the product

- Use of complementary feeding

- Anthropometrics

- Adverse events (frequency, type)

- Medication use

Study description

Background summary

The composition of Nutricia's current tube nutrition has recently been adjusted. The study product has become dominant in plant proteins compared to the current product, which is dominant in milk proteins. Before the new product will be launched on the market, it is important to establish that there are no concerns related to the GI tolerance of the product, that the product has no influence on nutritional intake and that the product is accepted by the patients and health care professionals.

The demand for plant (dominant) protein variants in medical food products is increasing and in the future, the use of milk proteins in medical food can be (partially) replaced by the use of plant proteins, resulting in a lower environmental impact.

Study objective

The objective of this study is to evaluate the gastro-intestinal tolerance, nutritional intake, and acceptability of an adjusted composition of an enteral tube feed for adults in need of long term nutritional support.

Study design

The study is an open label, exploratory study that will take place at multiple centers in multiple countries. Four products will be examined, all of which have the same adjusted product composition: Nutrison Standard, Nutrison Multifiber, Nutrison Energy, Nutrison Energy Multifiber. Each product will be examined in a separate study arm, which is why we call it a single arm study.

Intervention

Subjects will use their own current practice tube feed for 1 week (baseline period) and will switch to the intervention tube feed with an adjusted composition with a comparable energy density and fiber content as their current tube for 2 weeks (intervention period). In this way, there are 4 separate study groups as four difference products will be evaluated (n=20 per product group)

Study burden and risks

The burden on the patient is minimal. Patients are asked to answer a number of questions about the stool pattern and any gastrointestinal symptoms that may occur (2 times 7 days). After use of the intervention tube feed, it is possible that some stomach and intestinal related discomforts may occur, such as belching, flatulence, nausea, diarrhea or constipation. No risks are expected that may be related to the product or the study procedures.

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. Age >= 18 years
2. Using either an enteral tube feed with approximately 1.0 or 1.5 kcal/mL with or without added fibers via a nasogastric tube (NGT), nasojejunal (NJT) or Percutaneous Endoscopic Gastrostomy (PEG) for at least 4 weeks prior to screening
3. Actual and expected average daily intake of enteral nutrition at least 1000 kcal for at least 21 days after the start of baseline period
4. Written informed consent from subject (or impartial witness after verbal consent of subject)

Exclusion criteria

1. Subjects receiving total parental feeding (TPN)
2. Gastro-intestinal surgery or any other surgery involving general anaesthesia within 2 weeks prior to screening
3. Subjects with major hepatic or renal dysfunction in the opinion of the Investigator
4. Subjects currently in the intensive care unit
5. Active/flare up condition of chronic illnesses in small or large intestines in the opinion of the Investigator (e.g., active inflammation/flare up of Crohn*s disease or ulcerative colitis) within 2 weeks prior to screening,
6. Subjects experiencing cancer treatment-related diarrhea within 2 weeks prior to screening
7. Presence of colostomy or other faecal diversion
8. Known intolerance or allergy to ingredients of study product (e.g. galactosemia, allergy to soy)
9. Inability of the subject to answer the study diary or questionnaires due to e.g., being unconscious, cognitive impairment, or dementia, in the opinion of the Investigator
10. Known pregnancy or lactation
11. Investigator*s uncertainty about the willingness or ability of the subject to comply with the protocol requirements
12. Active participation in any other clinical study involving investigational or marketed products concomitantly or within four weeks prior to entry into the study in the opinion of the Investigator

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-05-2023
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	10-05-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL84024.056.23
Other	Registratie in CT.gov volgt