Effect of Plant Based High Energy High Protein Oral Nutritional Supplement on Nutritional Intake in Patients with or at Risk of Disease Related Malnutrition.

Published: 04-12-2024
Last updated: 18-01-2025

To investigate the effect of PB HEHP ONS compared to DB HEHP ONS on nutritional intake (energy & protein) in subjects with or at risk of DRM and/or prescribed with ONS.

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

Summary

ID

NL-OMON57157

Source
ToetsingOnline

Brief title
PRO-PLANT

Condition

- Other condition

Synonym
disease related malnutrition / malnutrition

Health condition

Ziekte gerelateerde ondervoeding

Research involving
Human

Sponsors and support

Primary sponsor: Danone Global R&I Center
Source(s) of monetary or material Support: Danone Global Research & Innovation Center B.V.

Intervention

Keyword: Disease Related Malnutrition (DRM), Oral nutritional support (ONS), Plant-Based

Outcome measures

Primary outcome

Main outcome of the study:

To investigate the effect of PB HEHP ONS compared to DB HEHP ONS on nutritional intake (energy & protein) in subjects with or at risk of Disease Related Malnutrition (DRM) and/or prescribed with ONS.*

Secondary outcome

other outcomes of the study:

To investigate the effect of PB HEHP ONS compared to DB HEHP ONS in subjects with or at risk of DRM and/or prescribed with ONS prior to the study on:*

- Safety and gastrointestinal (GI) tolerance*

- Compliance**

- Product experience & liking*

- Changes in anthropometry (BW, BMI)*

- Changes in blood nutrient status (Vitamin D (25(OH)D), ferritin, zinc,

calcium, parathyroid hormone (PTH)*

- Changes in percentage of subjects with or at risk of malnutrition according

to the Malnutrition Universal Screening Tool (MUST).*

- Changes in health-related quality of life (QoL) (EQ-5D-5L)*

- Changes in muscle strength & function (Hand Grip Strength & x 5 sit to stand

test).**

Study description

Background summary

The World Health Organization (WHO) reports the global prevalence of malnutrition showing that 462 million adults and about 2 billion people are underweight and suffer from micronutrient deficiency, respectively. According to the Medical Nutrition International Industry dossier the estimated number of people suffering from malnutrition in Europe is 33 million (MNI 2018). The prevalence of malnutrition can be associated with specific groups of disease and settings of care. Disease related malnutrition (DRM) is the consequence of inadequate dietary intake and nutritional support, and it can negatively impact the recovery of patients. Oral nutritional supplements (ONS) have proven clinical benefits for malnourished patients: ONS use is linked to lower mortality and lower complication rates when compared to standard of care. Historically, most ONS are made with dairy proteins, however, as more people transition to PB diets and the demand for products that do not contain animal derived ingredients grows, there is a growing request for PB ONS to meet this unmet need. Currently there are some PB ONS on the market, but very few that are high in energy and high in protein, and ready to drink. There is also very little evidence currently on plant based medical nutrition.*

Study objective

To investigate the effect of PB HEHP ONS compared to DB HEHP ONS on nutritional intake (energy & protein) in subjects with or at risk of DRM and/or prescribed with ONS.

Study design

This is a randomised controlled, double blind, parallel-group, multi-centre, multi-country, exploratory study.

Intervention

Subjects that are eligible for study participation will be randomly allocated to receive either the Test Product or the Control Product for a period of 8 weeks.

Study burden and risks

The burden on the subjects is kept minimal. Subjects are mainly asked to complete questionnaires and diaries during screening and/or the intervention period. The expected risks associated with the test and control products are minimal. During the intervention period, the number of visits to the research center (3x) and phone calls (2x) is limited . In consultation and if the site can facilitate (i.e. mobile blood collection), the visits can also take place at the participants' homes in order to relieve the participants. A large patient population can benefit from the results of the research.

Contacts

Public
Danone Global R&I Center

Uppsalalaan 12
Utrecht 3584 CT
NL
Scientific
Danone Global R&I Center

Uppsalalaan 12
Utrecht 3584 CT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age >= 18 years
2.Identified as at medium or high risk of malnutrition based on:
a) MUST score >= 1 and / or b)Being prescribed with ONS and willing and able to switch from pre-study prescribed ONS to the Test or Control Product for participation in the study
3. In need of 2 servings of ONS/day (400 kcal; 20 gr protein per serving) for at least 8 weeks as determined by the treating healthcare professional.
4. Medically and physically able to consume high energy high protein ONS in the opinion of the Investigator.
5. Willing to maintain dietary habits for the duration of the study.
6. Willing to consume plant based as well as dairy based ONS.

Exclusion criteria

1. Known allergy to soy, cow*s milk protein or to any other ingredients as listed in the study product composition (refer to the product information brochure (PIB) and the appendix of this protocol).
2. Known intolerance to any ingredients as listed in the study product composition (refer to PIB and appendix of this protocol). Subjects with lactose intolerance who use lactase may still be enrolled in the study.
3. Known galactosaemia
4. Any contraindication to oral feeding per se being: gastrointestinal failure or suppressed gastrointestinal function, complete intestinal obstruction and major intra-abdominal sepsis.
5. Active flare of inflammatory bowel disease as defined by Harvey-Bradshaw Index (HBI) >6 (Crohn*s disease) or Simple Clinical Colitis Activity Index (SCCAI) >5 (ulcerative colitis).
6. Recent history of gastrointestinal surgery (except appendectomy) that

interferes with the GI function, e.g. ileostomy, colostomy, (partial) gastrectomy or any other procedure for stomach volume reduction including gastric banding, within four weeks prior to the screening visit.
7. Requiring a protein restricted diet as confirmed by a physician, for example chronic kidney disease stage 4 and 5 (estimated by Glomerular Filtration Rate <30 mL/min/1.73 m2).
8. End stage renal disease (with renal replacement therapy e.g. haemodialysis or peritoneal dialysis), who may not require protein restriction.
9. Requiring enteral nutrition (via tube delivery) or parenteral nutrition.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	04-12-2024
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	NL87757.056.24
Other	Registratie in Clintrials.gov database volgt