Effect of an oral nutritional supplement (ONS) with prebiotic fibre compared to a non-fibre containing ONS equal in energy and protein content on gut microbiota bifidobacteria in older adults with or at risk of disease related malnutrition.

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The aim of this study is to determine the effects of prebiotic fibre delivered in ONS on the microbiome in older adults with or at risk of malnutrition and/or using ONS.

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

Summary

ID

NL-OMON57153

Source
ToetsingOnline

Brief title
BISON

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), Prebiotic fibre

Outcome measures

Primary outcome

The primary outcome parameter in this study is the change in gut microbiota

bifidobacteria levels (ΔV3-V1).

Secondary outcome

Secondary outcome parameters in this study are:

- Changes in gut microbiota composition (ΔV3-V1 analysed between and within

groups).

- Fecal pH and Total short-chain fatty acids (SCFA) (ΔV3-V1 analysed between

and within groups).

- Stool frequency and consistency assessed by the Bristol Stool Form Scale

(BSFS) (ΔV3-V1 analysed between and within groups)

Study description

Background summary

The World Health Organization (WHO) reports the global prevalence of malnutrition showing that around 390 million adults are underweight. According to the Medical Nutrition International Industry dossier, the estimated number

of people suffering from malnutrition in Europe is 33 million. The prevalence of malnutrition can be associated with specific groups of disease and settings of care. A large-scale survey performed in Ireland, UK, and The Netherlands highlights increased risk of malnutrition in hospitalized patients suffering from cancer, hematological, respiratory, and gastrointestinal disease. In the elderly population the prevalence of malnutrition is higher in the rehabilitation and long-term care (29.0%), hospitals (22.0%), and nursing homes (18.0%) compared to the home-care (9.0%) and outpatient services (6.0%) and the community (3.0%).

Disease related malnutrition (DRM) is the consequences of certain diseases in addition to inadequate dietary intake and nutritional support that negatively impact the recovery. In addition to DRM, several other factors such as the patient*s overall health status, age, prescribed medications (including antibiotics and chemotherapy), and poor dietary habits significantly influence recovery and clinical outcomes. The ageing process is linked with numerous changes in GI physiology and functionality. These changes can influence the quantity and variety of nutrients reaching the small intestine and colon, consequently altering the composition and functionality of the intestinal microbiota in these areas. Prebiotics are defined as 'a substrate that is selectively utilized by the host microorganisms conferring a health benefit' (e.g. soluble fibres).

Study objective

The aim of this study is to determine the effects of prebiotic fibre delivered in ONS on the microbiome in older adults with or at risk of malnutrition and/or using ONS.

Study design

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

A randomised controlled design is chosen for reason of scientific credibility. The study is designed as a double-blind study. As it might be hard to enrol the study target population in studies collecting stool samples a multi-country set up has been chosen; the Netherlands and Belgium.

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 4 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 is limited (3x). In consultation, 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

1. 65 years of age or older
2. Identified as at medium or high risk of malnutrition based on:
a) MNA-SF score between 0 - 11 and / or

b) are prescribed with ONS
3. In need of 2 servings of oral nutritional support/day (300 kcal; 12 gr protein per serving).
4. Willing to maintain dietary habits for the duration of the study.
5. Written informed consent from subject.
6. Have access to a freezer and willing to store the stool samples in it.

Exclusion criteria

1. Requirement for a fibre-free diet.
2. Have used nutritional supplements with fibre/prebiotics and/or probiotics content at any point during 3 weeks prior to start study (V1) and / or will not refrain from using these kinds of products during the study period.
3. Admitted to hospital.
4. Excessive alcohol consumption (use of > 10 units per week or > 2 units per day on average during the past 6 months).
5. Active smoker (1 cigarette or more per week) or quit smoking less than 5 years ago.
6. Known allergy to cow*s milk protein.
7. Known allergy to soy protein
8. Known galactosaemia.
9. Known hepatic encephalopathy.
10. Any antecedents of digestive surgery (except for appendectomy and cholecystectomy performed more than 2 years before the screening visit), or plan for such surgery during the study.
11. Known Irritable Bowel Syndrome.
12. Known lactose intolerance without using lactase.
13. Known history of intestinal polyp removal within 3 months prior to the study.
14. Known history of Immunotherapy.
15. Known history of GI cancer.
16. Active cancer treatment or within 12 months prior the study
17. Diagnose of Celiac Disease.
18. Received antibiotics (systemic) within 4 weeks prior to study.
19. Patients following a vegan or vegetarian diet.
20. Active flare of inflammatory bowel disease as defined by HBI >6 (Crohn*s disease) or SCCAI >5 (ulcerative colitis).
21. Stricturing Crohn*s disease.
22. Any contraindication to oral feeding per se being: gastrointestinal failure or suppressed gastrointestinal function, complete intestinal obstruction and major intra-abdominal sepsis.
23. Investigator*s uncertainty about the willingness or ability of the subject to comply with the protocol requirements, for example due to the presence of a psychiatric disorder (e.g. major depression, psychoses), dementia or Alzheimer*s disease.

24. Planned hospital admission during the study.
25. Planned dental surgery during the study.
26. Participation in any other studies involving investigational or marketed products concomitantly or within 6 weeks prior to baseline.
27. Severe disease with life expectancy less than a year.
28. If the subject is unable to sign the Informed Consent themselves.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2024
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2024
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	NL87452.056.24
Other	Registratie in CT.gov volgt