Protein intake in patients with colorectal or lung cancer during first line treatment with chemo(radio)- or immunotherapy when receiving a low volume, energy dense and high protein oral nutritional supplement: a randomized, controlled study

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Ethical review	Not approved
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50399

Source
ToetsingOnline

Brief title
PROTEOS study

Condition

- Other condition

Synonym
cancer cachexia, weight- and muscle loss

Health condition

kanker cachexie, ondervoeding bij kanker

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Colorectal cancer, Lungcancer, Medical Nutrition

Outcome measures

Primary outcome

The average protein intake per day corrected for baseline after 1 cycle of

first line treatment with chemo-, concurrent chemoradio- or immunotherapy

(3-day food diary)

Secondary outcome

Secondary and exploratory outcomes of the study are:

• Body weight

• Proportion of subjects with a protein intake >=1.0 g/kg/day (3-day food

diaries + 1-day food diaries

• Total dietary energy intake, macronutrient intake, micronutrient intake

(3-day food diaries + 1-day food diaries)

• Factors impacting nutritional intake (question with each food diary)

• Taste and smell changes (questionnaire)

• Health-related Quality of Life (EORTC QLQ-C30 and QLQ-CAX24, in a subgroup)

• Tolerance questionnaire

• Performance status (ECOG)

• Anti-cancer treatment adherence and dose-limiting toxicities

• Body composition from CT scan (optional, when data available from routine

clinical care)

Study description

Background summary

There is a strong body of evidence showing that cancer-related malnutrition, and in particular muscle wasting, is a negative prognostic factor for quality of life, response to treatment and occurrence of chemotherapy toxicities as well as survival. Malnutrition results from the combination of reduced food intake and increased catabolism in cancer patients. Therefore, maintaining a sufficient energy and protein intake during treatment is key. Achieving protein intake recommendations is challenging for many patients undergoing treatment. Patients may benefit more from a protein-dense nutritional supplement to support nutritional intake, and more specifically protein intake during treatment.

Study objective

The primary study objective is to assess protein intake at the end of the first treatment cycle in patients with CRC or NSCLC undergoing first line treatment with chemo-, concurrent chemoradio- or immunotherapy who are receiving two servings of test product daily and who completed the study until the end of the first treatment cycle compared with standard of care.

Secondary objectives of this study are:
in patients with CRC or NSCLC undergoing first line treatment with chemo-, concurrent chemoradio- or immunotherapy who are receiving two servings of the test product daily or who are receiving standard of care:
- To study the proportion of subjects with a protein intake above the lower limit of the ESPEN recommendations for protein intake for cancer patients at the end of the first treatment cycle
- To study the effect of the test product on body weight during 12 weeks

Exploratory objectives are in these patients:
• To assess protein intake at the end of the second or third treatment cycle

(depending on the duration of a treatment cycle), i.e. after 6-8 weeks of treatment
• To study the proportion of subjects with a protein intake above the lower limit of the ESPEN recommendations for protein intake for cancer patients at the end of the second or third treatment cycle (depending on the duration of a treatment cycle) and after 12 weeks of treatment
• To gain insight on:
o Dietary intake and factors impacting dietary intake over the course of treatment
o Taste and smell changes
• To study the effect of the test product on:
o Health-related quality of life
o Performance status
o Treatment adherence and dose-limiting toxicities
o Body composition (optional, when data are available from routine clinical care)

Study design

This is a randomised controlled, open label, parallel-group, multi-center and multi-country study. A 2:1 randomisation will be applied.

Intervention

The test group will be receiving daily 2 servings of a low volume, energy dense and high protein oral nutritional supplement during 12 weeks of first line treatment. The control group will be receiving standard of care.

Study burden and risks

Patients in the test group will be asked to take the medical nutrition supplement (test product) twice daily during the first 12 weeks of their first line anti-cancer treatment. They will start taking the test product at least 1 but preferably 4 or more days before the start of the first treatment cycle. The control group will receive standard of care. Patients in the control group will undergo the same assessments as patients in the test group. Most of the study assessments are performed during routine hospital visits required for the treatment of the disease. In addition, some of the assessments will be done at home. Study specific assessments are: daily recording of test product intake in a diary (for the test group only) and completing 3-day and 1-day food diaries, questionnaires to record factors impacting nutritional intake, gastrointestinal symptoms, quality of life and taste and smell changes. Based on literature, no specific adverse effects are expected. Adverse events, treatment adherence and dose-limiting toxicities will be evaluated.

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. Histologically proven CRC stage IIB, III or IV or histologically or cytologically proven NSCLC stage III or IV
2. Eligible and scheduled for first line chemotherapy, concurrent chemoradiotherapy or immunotherapy treatment with a planned duration of at least 12 weeks
3. Performance status Eastern Cooperative Oncology Group (ECOG) score 0 or 1
4. Age >= 18 years
5. Written informed consent

Exclusion criteria

1. Scheduled for first line chemotherapy, concurrent chemoradiotherapy or immunotherapy treatment starting <=4 days after randomization
2. Received >10 doses of radiotherapy within 2 months prior to the study
3. Weight loss >10% in the last 6 months
4. Body Mass Index < 20.0 kg/m2
5. Life expectancy < 3 months
6. Prescription of oral nutritional supplementation (ONS) before start of first line treatment based on hospital*s standard practice
7. Presence of ileostoma or ileal pouch
8. Contra-indications to oral feeding, high protein nutrition or to the test product (including galactosaemia) in the opinion of the investigator
9. Known pregnancy or lactation
10. Current alcohol or drug abuse in the opinion of the investigator
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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2019
Enrollment:	40
Type:	Actual

Ethics review

Not approved Date:	09-02-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-10-2020
Application type:	Amendment
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	NL64202.056.17