Protein intake in patients with colorectal or lungcancer when receiving a nutritional supplement

No registrations found.

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

Summary

ID

NL-OMON27071

Source
Nationaal Trial Register

Brief title
PROTEOS

Health condition

Colorectal and lungcancer

Sponsors and support

Primary sponsor: Nutricia Research B.V.
Uppsalalaan 12
3508 CT Utrecht, the Netherlands
Source(s) of monetary or material Support: Nutricia Research

Intervention

Outcome measures

Primary outcome

To assess protein intake at the end of the first treatment cycle

Secondary outcome

- Proportion of subjects with a protein intake above the lower limit of the ESPEN recommendations for protein intake

- Body weight

Study description

Background summary

study ended prematurely due to COVID. No summary available.

Study objective

a higher 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.

Study design

Visits consist of: Screening, Baseline, Randomization, 1st day of each cycle, week 12 visit, week 13 follow up phone call.

Some questionnaires and diaries must be completed at home during the 13 week period. Timing depends on the treatment (2, 3 or 4 week treatment schedule)

Intervention

Duration of intervention: approximately 13 weeks

Intervention group: receiving two units of test product per day for oral intake for a period of approximately 13 weeks.

Control group: receiving standard of care, ie nutritional support as regularly provided by the hospital,

Contacts

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Eligibility criteria

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 ¡Ý 18 years

5. Written informed consent

Exclusion criteria

1. Scheduled for first line chemotherapy, concurrent chemoradiotherapy or immunotherapy treatment starting ¡Ü4 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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-10-2018
Enrollment:	126
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-10-2018
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	NL7297
NTR-old	NTR7506
Other	Nutricia : MPR16TA06151

Study results