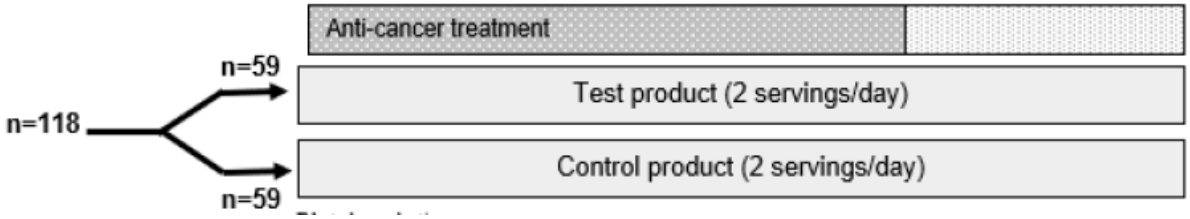
Allies

Muscle mass in patients with colorectal or lung cancer when receiving a n-3 PUFA and leucine enriched high protein and high energy oral nutritional supplement during anti-cancer treatment

This is the trial summary as assessed on clinicaltrials.gov. You can check this on this direct link: Study Details | Effect of an Oral Nutritional Supplement on Muscle Mass During Anticancer Treatment | ClinicalTrials.gov

Trial design



Inclusion criteria

1. Diagnosis of stage III or IV colorectal or non-small cell lung cancer
2. Scheduled for the first cycle of any line of a systemic treatment: chemotherapy, concurrent chemoradiotherapy, immunotherapy or targeted treatment with a planned duration of at least 9 weeks
3. BMI-adjusted weight loss grade from 1 to 3, both inclusive, according to the grading system by Martin et al 2015 [60] and BMI ≤35 kg/m2
4. Performance status Eastern Cooperative Oncology Group (ECOG) score 0 or 1
5. Baseline CT scan including L3 vertebrae available (max. 31 days before baseline) or the willingness to have CT scan as a baseline assessment
6. Age ≥ 18 years
7. Written informed consent

Exclusion criteria

1. Life expectancy < 3 months
2. Receiving enteral (tube) or parenteral nutrition
3. Received >10 doses of radiotherapy within 2 months prior to the study
4. Taking fish oil supplements within 4 weeks prior to the baseline CT scan and the baseline visit
5. Receiving less conventional chemo- or radiotherapy treatment regimes (e.g. HIPEC) in the opinion of the investigator
6. Presence of an ileostomy or ileal pouch (except for an ileostomy at or near the terminal ileum which does not affect absorption of nutrients other than sodium, potassium, and water, in the opinion of the investigator)
7. Severe renal dysfunction (estimated Glomerular Filtration Rate (eGFR) <29 ml/min/1.73m2 or albumin:creatinine (ACR) > 30) or hepatic encephalopathy
8. Severe hypercalcemia, i.e. total calcium level corrected for albumin >14.0 mg/dL (>3.5 mmol/L)
9. Allergy to cow's milk protein, soy or fish, requiring a fibre-free diet or suffering galactosemia or lactose intolerance

10. Known pregnancy or lactation
11. Current alcohol or drug abuse in the opinion of the investigator
12. Wearing an electronic implant and/or pacemaker
13. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements
14. Participation in any other studies involving investigational or marketed products concomitantly or within 14 days prior to entry into the study