RESEARCH TOPIC DASMEN3

EARLY INTRAVENOUS ADMINISTRATION OF NUTRITIONAL SUPPORT (IVANS) IN METASTATIC GASTRIC CANCER PATIENTS AT NUTRITIONAL RISK, UNDERGOING FIRST-LINE CHEMOTHERAPY: A PRAGMATIC, RANDOMIZED, MULTICENTER, PARALLEL-GROUP, CLINICAL TRIAL

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Abstract
Malnutrition is common in cancer patients and negatively affects treatment tolerance, survival, functional status, and quality of life (QoL). Nutritional support, including supplemental parenteral nutrition (SPN), is recommended in malnourished cancer patients. Studies regarding the early administration of SPN in combination with nutritional counseling (NC) are lacking.
The aim of this project is to evaluate the efficacy in terms of survival, weight maintenance, body composition, QoL and feasibility of cancer therapy of early systematic SNP, in combination with NC, compared to NC alone, in metastatic gastric cancer patients at nutritional risk undergoing first-line chemotherapy (CT). The proposed project guarantees the early provision of nutritional assessment and support to all the enrolled patients, could demonstrate the clinical effectiveness of early intensive nutritional support in cancer patients undergoing CT, and may result in the improvement of supportive care quality.

Main technical approaches
Enrollment is expected to last about 36 months. Follow-up is expected to be 12 months from enrollment.
The following data will be collected during the scheduled visits in relation to the cancer treatment protocol and follow-up:
• General demographic and clinical data
• Anthropometric data: Body weight, 6-month and 1-month previous unintentional weight loss (WL), height, and body mass index (BMI)

• Caloric-protein needs: Energy requirements will be estimated by multiplying the resting energy expenditure (calculated using the Harris–Benedict equation) by a correction factor of 1.5 [in obese patients (BMI >30 kg/m2) ideal body weight at a BMI = 23 kg/m2 will be used in the equation], while protein requirements will set to 1.5 g/kg of actual body weight (or ideal body weight in obese patients)
• Oral, by SPN and total caloric-protein intake
• Nutritional risk: assessed at the screening visit using the NRS-2002 screening tool, based on the information collected on BMI, 6-month unintentional WL, food intake, diagnosis, and age
• Symptoms, laboratory tests
• Assessment of functional status: muscle strength (handgrip strength) by digital dynamometer
• Body composition by vector bioimpedenzometry: resistance and reactance will be measured by calculating phase angle (PhA), standardized PhA, and hydration index
• Muscle mass by computed tomography: muscle area will be quantified on scans at L3, collected at baseline and subsequent reassessments for the evaluation of the response to CT
• QoL, adverse events, compliance
• Immunologic profile in a subgroup of patients (exploratory endpoint): measurements obtained using multiple tools will be integrated with the aim of analyzing different cell subsets, their functionality, and soluble molecules in the peripheral blood. Serum and plasma will be analyzed using the Luminex technology for the assessment of 30 soluble factors associated with the inflammatory and immunoregulatory states together with the patients' cellular immunologic profiles using 18-color flow cytometry

The primary outcome will be a composite of 1-year overall survival (OS) or the absence of unintentional WL ⩾10% of weight recorded at
enrollment. All the other above mentioned data will be evaluated as secondary endpoints.
OS will be compared using the log-rank test. The relative risk and its
95% confidence interval (CI) will be derived from a Cox model. A multivariable secondary analysis
of the primary endpoint will also be performed while adjusting for age, gender, BMI, PhA, and hydration index, as confounding factors at
recruitment. Further statistical analyses will be performed in specified subgroups of patients.

Scientific references

Caccialanza R et al. Early intravenous administration of nutritional support (IVANS) in metastatic gastric cancer patients at nutritional risk, undergoing first-line chemotherapy: study protocol of a pragmatic, randomized, multicenter, clinical trial. Ther Adv Med Oncol 2020; 12:1-11

Pedrazzoli P et al. Advantages Of Clinical Nutrition Use In Oncologic Patients In Italy: Real World Insights. Healthcare (Basel) 2020;8:e125

Caccialanza R et al. Unmet needs in clinical nutrition in oncology – a multinational analysis of real-world evidence. Ther Adv Med Oncol 2020;12:1-10

Caccialanza R et al. Nutritional Support in Cancer Patients: A Position Paper from the Italian Society of Medical Oncology (AIOM) and the Italian Society of Artificial Nutrition and Metabolism (SINPE). J Cancer 2016;7:131-135

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Caccialanza R et al. Phase angle and handgrip strength are sensitive early markers of energy intake in hypophagic, non-surgical patients at nutritional risk, with contraindications to enteral nutrition. Nutrients 2015;7:1828-1840

Type of contract

PhD scholarship of € 18.000 gross per year or equivalent contract.

Borsa di dottorato di € 18.000 annui lordi o forme di sostegno finanziario equivalenti.

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