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A tailored exercise and nutritional intervention for improving early-stage NSCLC outcomes: the STARLighT study

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Introduction. Observational evidence links exercise to longer survival, but to date, no causality has been demonstrated. The primary aim of the STARLighT trial is to evaluate the impact of a structured exercise and nutrition intervention on pathological complete response (pCR) in patients undergoing neoadjuvant treatment and on disease-free survival (DFS) in patients undergoing adjuvant treatment.
Methods. Two cohorts of patients with non-oncogene addicted with early-stage non-small cell lung cancer (NSCLC), stages IB to IIIA, will be enrolled. COHORT A will accrue 46 patients undergoing neoadjuvant chemo/immunotherapy and exploit a single-arm phase II design to detect an increase in the proportion of pCR from 20% to 40%; COHORT B will accrue 278 patients undergoing physician's choice of adjuvant treatment and exploit a 1:1 randomized controlled design to detect an increase in 2-year DFS rates from 55% to 70% in the control and experimental arms, respectively. All patients in COHORT A will receive a personalized exercise intervention thrice a week, tailored nutritional counseling, and immunonutrients, two bottles/day. The intervention in COHORT A will last for the entire neoadjuvant treatment period. In COHORT B, whereas patients randomized in the controls will receive the current standard of care and dedicated educational health material, those allocated in the experimental arm will undergo exercise twice a week, nutritional counseling, and whey protein, 20 gr/day. The intervention for the COHORT B will last 6 months. Translational studies will encompass baseline assessment of genomic and transcriptomic features and longitudinal assessment of circulating immuno-inflammatory profiles and tumor microenvironment composition, to be correlated with clinical and lifestyle data to build a comprehensive predictive model.

Conclusion. We expect that a tailored lifestyle intervention will result in a higher pCR rate and longer DFS in patients in the neoadjuvant or adjuvant setting, respectively, thereby potentially increasing cure rates in early NSCLC.

Keywords

Exercise; nutrition; lung cancer; clinical outcomes;

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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