TPS12143 Poster Session

Supervised home-based exercise in patients with advanced non-small cell lung cancer (NSCLC) on maintenance immune checkpoint inhibitors (ICI).

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Background: Lung cancer is the leading cause of cancer-related mortality in the US and results in significant morbidities, including fatigue, depression, and decreased quality of life. Exercise has been shown to reduce severity of fatigue and depression while improving cardiorespiratory fitness (CRF) in patients with lung cancer. Past trials have primarily investigated exercise interventions in patients who received surgery and/or chemotherapy; data on the impact of exercise in patients with lung cancer on immune checkpoint inhibitors (ICI) has been sparse. Following the advent of ICI as maintenance therapy in advanced lung cancer, patients have experienced improved survival and more favorable toxicity profile that better positions them to both participate in and derive benefit from an exercise program. In addition, exercise is expected to promote a patient's response to ICI by promoting mobilization of natural killer-cells and T-cells. Already observed in animal and patient derived xenograft models, the combination of exercise and ICI reduced tumor growth by influencing the tumor microenvironment, increasing tumor infiltrating lymphocytes. In this trial, we are investigating the impact of a supervised home-based exercise program on fatigue, depression, CRF, physical function, muscle mass and biomarkers of immune activation in patients with advanced lung cancer on maintenance ICI. **Methods:** This prospective, randomized phase II trial (NCT06513663) aims to enroll 86 patients with advanced NSCLC receiving maintenance ICI. Patients are randomized 1:1 to an exercise intervention or usual care, stratified by baseline frailty as determined by short physical performance battery (SPPB). Eligible patients have locally advanced (stage III) or metastatic (stage IV) NSCLC and are currently receiving maintenance ICI for at least 1 month with plans for at least an additional 3 months of therapy. The trial is targeting an enrollment of 3-4 patients per month over a period of 2 years, and began in June 2024. Patients randomized to exercise participate in 60-minute sessions including aerobic, resistance, and balance exercises, delivered virtually three days per week for 12 weeks by a professional trainer. The primary endpoint is the change in patient-reported fatigue using the Functional Assessment of Cancer Therapy: Fatigue (FACT-F) questionnaire from baseline to post-intervention, compared between the intervention and usual care. Secondary endpoints include changes in patient-reported depression using Hospital Anxiety and Depression Scale (HADS), muscle mass on CT scan, CRF by VO_{2peak} on a ramp treadmill test, objective and subjective physical function, and adherence to exercise intervention. Exploratory analysis will include changes in circulating tumor cells and T-cell subsets. Patients will be followed post-intervention for up to 2 years. Clinical trial information: NCT06513663. Research Sponsor: None.