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Exercise training in patients with malignant melanoma undergoing neoadjuvant checkpoint inhibitor therapy –NEO-MEL TRAIN

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Background:
Since introduction of immune checkpoint inhibitors, the prognosis of melanoma has improved markedly in both adjuvant and metastatic settings. More recently, neoadjuvant therapy has emerged as an alternative to adjuvant treatment and has shown encouraging clinical and pathological outcomes for patients with melanoma, although long-term survival data are still maturing. Exercise training (ET), an emerging focus in oncology, enhances physical capacity, improves quality-of-life, reduces emotional distress, and modulates immune function in can-cer patients. However, prospective data—particularly on ET combined with immunotherapy—remain limited. This study aims to investigate the impact of structured ET in patients undergo-ing neoadjuvant immunotherapy for resectable stage III melanoma.

Objective:
The NEO-MEL TRAIN trial investigates whether supervised ET can improve cardiorespiratory fitness and patient-reported outcomes, and tumor- and immune-related biomarkers in mela-noma patients receiving neoadjuvant immunotherapy.

Methods:
This phase II randomized trial will include 60 patients with resectable stage III melanoma scheduled for neoadjuvant immunotherapy at Herlev Hospital or Odense University Hospital. Patients will be randomized 1:1 to receive standard-of-care neoadjuvant immunotherapy alone or in combination with an 8-week supervised, cycle-based interval training program performed three times weekly at moderate-to-high intensity. The intervention is delivered us-ing a decentralized, home-based model, with remote supervision.

The primary endpoint is change in cardiorespiratory fitness after 8 weeks, measured by VO_2max with an incremental cycling test. Secondary endpoints include patient-reported quali-ty of life and emotional distress (EORTC QLQ-C30, HADS). Exploratory endpoints include immune responses, tumor microenvironment features, circulating tumor DNA, gut microbi-ome, and treatment-related adverse events.

Conclusion:
This trial will provide prospective, randomized evidence on feasibility and potential benefits of structured ET during neoadjuvant immunotherapy for patients with melanoma and may help inform future integrative and supportive treatment strategies.

Research Plan
The trial is expected to initiate in the first quarter of 2026, subject to regulatory approvals

Keywords

Neoadjuvant immunotherapy, Exercise training, Melanoma, Immunomodulation

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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