

Exercise to Boost Response to Checkpoint Blockade Immunotherapy

NCT06008977

Status	RECRUITING
Phase	Not Applicable
Sponsor	AdventHealth Translational Research Institute
Enrollment	20 participants

Plain Language Summary

This trial is studying whether a structured exercise program can boost the effectiveness of immunotherapy (specifically checkpoint blockade drugs) in cancer patients. Participants will be randomly assigned to an exercise group or a standard care group while receiving their scheduled immunotherapy.

****You may be eligible if...****

- You are 18 or older
- You can read and speak English
- You are able to walk unaided for at least 6 minutes
- You are scheduled to start immunotherapy (avelumab, cemiplimab, ipilimumab, nivolumab, or pembrolizumab) for melanoma, squamous cell skin cancer, or Merkel cell carcinoma
- You are willing to follow the prescribed exercise plan and complete study forms

****You may NOT be eligible if...****

- You have a serious heart condition that makes exercise unsafe
- You have major complications from recent surgery
- You have an active contagious disease such as tuberculosis, active hepatitis B or C, HIV, or COVID-19
- You are receiving other cancer treatments alongside immunotherapy (e.g., targeted therapy)

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (8)

- Males and females e18 years of age.
- Able to read and speak English fluently.
- Reported ability to complete 20-30 minutes moderate exercise per positive response to, "Can you currently walk unaided for six minutes or more?"
- Scheduled for first-time checkpoint blockade immunotherapy with avelumab, cemiplimab, ipilimumab, nivolumab, or pembrolizumab in the absence of other therapies (e.g. targeted therapy) with the following diagnosis:
- Adjuvant setting: cutaneous melanoma.
- ... and 3 more (see full listing online)

Exclusion (5)

- Presence of medical conditions, such as severe cardiovascular disease for which exercise may be contraindicated. Participants may be referred to their medical team to obtain a cardiology approval.
- Presence of major postoperative complications for which an exercise intervention may be contraindicated.
- Currently has a chronic, contagious, infectious disease, such as active tuberculosis, active Hepatitis B or C, HIV, or COVID-19, per self-report.
- Currently pregnant, lactating or planning to become pregnant (positive result on urine pregnancy testing).
- Presence of any condition that, in the opinion of the Investigator, compromises participant safety or data integrity or the participant's ability to complete the study.

<https://clinicaltrials.gov/study/NCT06008977>

Locations (1 total)

AdventHealth Translational Research Institute, Orlando, Florida, United States

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