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Promoting IMmunotherapy by Exercise in patients with advanced Renal cell carcinoma (PRIMER)

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Background:

Immune checkpoint inhibitors (ICIs) have become standard of care first-line therapy for patients with advanced renal cell carcinoma (aRCC). Although ICIs improve survival, treatment outcomes are limited due to primary and secondary resistance as well as immune-related adverse events (irAEs). Preclinical work suggests that exercise may enhance antitumor immunity, reduce immunosuppression within the tumor microenvironment and potentially improve ICI efficacy, with the microbiome playing a key role in this process. However, the feasibility, safety and mechanistic effects of exercise during immunotherapy in patients with aRCC remains unknown.

Objectives:

The PRIMER trial is a pilot randomized controlled trial that aims to evaluate the feasibility and safety of supervised high-intensity interval training (HIIT) during first-line combination ICIs therapy (nivolumab + ipilimumab) in patients with aRCC. Preliminary effects of HIIT on immune status and microbiome are explored as well as physiological and patient-reported outcomes (PROs).

Methods:

30 patients with aRCC initiating first-line dual ICI therapy will be randomized 1:1 to the exercise intervention or usual care arm. Patients in the exercise group will complete two 60-minute exercise sessions per week, including moderate intensity aerobic exercise and HIIT supervised by oncology-specialized physiotherapists during 4 treatment cycles. Primary outcomes are feasibility as defined by exercise adherence, retention to the exercise program, and the incidence of (immune-related) adverse events (irAEs). Secondary outcomes include immune cell phenotype and function (NK cells, CD8+ T cells), cytokines, physical fitness, PROs and clinical endpoints (overall response rate, progression-free survival, overall survival). Blood and fecal sampling will occur prior to treatment and after 2 and 4 cycles of immunotherapy.

Expected impact:

This pilot trial will provide insights into feasibility, irAEs and antitumor immune responses of exercise during ICI treatment in aRCC. Patient recruitment will start in February 2026.

Keywords

Renal cell carcinoma; immunotherapy; Exercise oncology; High-intensity interval training

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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