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Food intervention trial to reduce immunotherapy toxicity (FORX): Impact of a weekly 30-plant diet on immune related adverse events

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Background

Preclinical and retrospective studies suggest that gut microbiome composition influences outcomes in patients treated with immune checkpoint inhibitors (ICI), with greater microbial diversity associated with improved oncological responses and lower risk of immune-related adverse events (irAEs). Dietary fiber intake is a key modulator of the gut microbiome. Consuming at least 30 different plants per week (vegetables, fruits, legumes, nuts, and seeds) has been associated with greater microbial diversity.

Methods

The FORX trial (NCT05832606) is a prospective, single-arm interventional study evaluating a 30-plant-per-week diet during the first 12 weeks of ICI treatment in patients with solid tumors treated at UZ Brussel, a Belgian tertiary oncology center. The primary endpoint is irAE incidence. Secondary endpoints include gut microbiome composition and oncological response.

Results

Enrollment was completed in June 2026. At the September data cut-off, 54 patients were evaluable for the 12-week primary endpoint after 7 early discontinuations. Median age was 62 years (range 34-87). Treatment consisted of anti-PD(L)1 monotherapy in 33 patients (61.1%), anti-PD1 plus anti-CTLA4 in 14 (25.9%), and anti-PD1 plus anti-LAG3 in 7 (12.9%). Melanoma was the most common tumor type (30/54, 55.6%) and 23 patients (42.6%) had metastatic disease. Mean fiber intake increased from 20.2 g/day at baseline to 28.8 g/day during the intervention, corresponding to a mean within-patient increase of 8.5 g/day (95% CI 6.7-10.4; paired t-test, p<.001). Of 47 patients analysed to date, 35 (74.5%) achieved a mean fiber intake ≥25 g/day. Over 12 weeks, 28 of 54 patients experienced at least one irAE (51.9%; 95% CI 38.9–64.6%), including 2 with grade ≥3 toxicity (3.7%; 95% CI 1.0–12.5%); 6 required systemic immunosuppression (11.1%; 95% CI 5.2–22.2%).

Conclusions

A 30-plant-per-week dietary intervention during ICI treatment was feasible, significantly increased dietary fiber intake, and was accompanied by a low incidence of grade ≥3 toxicity. These findings provide a basis for integrated analyses of the complex relationships between diet, the gut microbiome, patient characteristics, and clinical outcomes during immunotherapy.

Clinical trial identification

NCT05832606.

Legal entity responsible for the study

UZ Brussel.

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Disclosure

All authors have declared no conflicts of interest.

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