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Supplementary information

Roles of the gut microbiota in immune-related adverse events: mechanisms and therapeutic intervention

In the format provided by the authors and unedited

Supplementary Table 1 | Ongoing clinical trials evaluating gut microbial modulation or gut microbial biomarkers for irAEs

Clinical trial title	ClinicalTrials.gov ID	Location	Summary
Stool transplant to control treatment-related diarrhoea	NCT04883762	New York, United States	**Study type:** An interventional study
			Participants: Patient has been treated with ICI for any malignant indication and has developed diarrhoea grade ≥2 attributed to ICI, which persists despite treatment with corticosteroids for at least 72 hours and/or at least one dose of a biologic medication, such as infliximab or vedolizumab, with symptoms that persist or recur at least 72 hours post-infusion.
			Intervention: Faecal microbiota transplantation via colonoscopy
			Study size: 4
			Study start date: 2021.05.10
			Study completion date (estimated): 2026.05
			Primary Outcomes: Incidence of faecal microbiota transplantation-related adverse events
Faecal microbiota transplantation in checkpoint inhibitor-mediated diarrhoea and colitis	NCT06206707	Aarhus N, Denmark	**Study type:** A randomized, placebo-controlled trial
			Participants: Patients of malignant melanoma and/or kidney cancer have been treated with any ICI within the last 8 weeks and developed grade 2 or higher diarrhoea.
			Intervention: capsule faecal microbiota transplantation
			Study size: 20
			Study start date: 2024.01.23
			Study completion date (estimated): 2025.03.31
			Primary Outcomes: Clinical remission of immune-mediated diarrhoea
Role of gut microbiome and faecal transplant on medication-induced gastrointestinal complications in patients with cancer	NCT03819296	Houston, Texas, United States	**Study type:** An interventional study
			Participants: Patients with any stage melanoma, non-small-cell lung cancer or genitourinary malignancies (Project 1) or patients with any cancer type (Projects 2 and 3) have been treated with any ICI agent and developed ICI related diarrhoea and/or colitis.
			Intervention: Project 1: standard of care and collection of stool and blood samples. Projects 2: drugs including prednisone, infliximab, or vedolizumab and collection of stool, blood, and tissue samples. Projects 3: faecal microbiota transplantation.
			Study size: 800
			Study start date: 2021.02.21
			Study completion date (estimated): 2025.10.31
			Outcomes: Difference in stool microbiome pattern and incidence of adverse events of faecal microbiota transplantation

Food intervention to reduce immunotherapy toxicity	NCT05832606	Jette, Belgium	**Study type:** A prospective interventional cohort study
			Participants: Patients with solid tumours who were treated with anti-PD-1 and/or anti-CTLA4 antibodies as part of standard of care
			Intervention: Food box containing 30 different plants
			Study size: 60
			Study start date: 2024.01.01
			Study completion date (estimated): 2026.12.31
			Primary Outcomes: Feasibility of performing a dietary intervention trial in the centre and Incidence of immune related adverse events
Fasting mimicking diet for reducing immune related adverse events for cancer patients on immune checkpoint inhibitors	NCT06438588	Jacksonville, Florida, United States	**Study type:** An interventional study
			Participants: Patients with advanced stage malignancies (stage 3 or 4) undergoing immunotherapy for their first time
			Intervention: fast mimicking diet
			Study size: 10
			Study start date: 2024.03.06
			Study completion date (estimated): 2027.03.15
			Primary Outcomes: Symptom measurement, incidence of adverse events, physical function, quality of life, and faecal calprotectin.

ICI, immune-checkpoint inhibitor; irAEs, immune-related adverse events