RENAL CELL CANCER

Fecal microbiota transplantation to improve efficacy of immune checkpoint inhibitors in renal cell carcinoma (TACITO trial).

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Abstract Disclosures

Abstract

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Background: Renal cell carcinoma (RCC) is the 6° most common cancer in men and the 8° in women in the USA. In Italy RCC incidence was 11,500 new cases in 2017, while mortality was 3,371 cases in 2015. Increasing evidence suggests that response to immune checkpoint inhibitors (ICIs), a novel treatment for advanced RCC (aRCC) and other epithelial tumors, can be influenced by the patient gut microbiota. Fecal microbiota transplantation (FMT) is a novel treatment option aimed to restore healthy gut microbiota, and is the most effective therapy for recurrent *C. difficile* infection. Preliminary nonrandomized findings show that FMT is able to improve efficacy of ICIs in patients with advanced melanoma. The aim of this study is to evaluate, through a double-blinded placebo-controlled randomized clinical trial, the efficacy of targeted FMT (from donors who are responding to ICIs) in improving response rates to ICIs in subjects with aRCC. **Methods:** 50 patients who are about to receive, or have started by <8 weeks, pembrolizumab + axitinib as first-line therapy for aRCC will be enrolled. Exclusion criteria include major comorbidities, concomitant GI or autoimmune disorders, or HIV, HBV, HCV infection, continuative

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corticosteroid therapy, previous treatment with systemic immune-suppressants or immune-modulatory drugs, antibiotic therapy within 4 weeks prior to enrollment. Stool samples and clinical data will be collected at baseline. Then, patients will be randomized to donor FMT or placebo FMT. They will receive the first infusion by colonoscopy and then oral frozen fecal or placebo capsules (8 capsules t.i.d.) 90 and 180 days after the first FMT. Stool donors will be searched among long-term (>12 months) responders to ICIs, and will be selected by following protocols recommended by international guidelines. Patients in the FMT group will always receive feces from the same donor throughout the three fecal transplants. Frozen fecal batches and frozen fecal capsules will be manufactured according to international guidelines. Patients will be followed-up 7, 15, 30, 90, 180, 270, and 360 days after randomization for clinical evaluation and collection of stool samples. Patients will also undergo radiological assessment at 90, 180, 270 and 360 days after randomization. Microbiome analysis will be performed with shotgun metagenomics. The primary endpoint is the progression-free survival (PFS) at 12 months. Secondary endpoints are: objective response rate at 12 months; overall survival at 12 months; adverse events after FMT; microbiome changes after FMT. Sample size calculation was based on the hypothesis that FMT can improve the 1-year PFS rate from 60% (reported 1-year PFS for SOC) to 80% wen associated to SOC. Clinical trial information: NCT04758507.

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