TPS2702 **Poster Session**

Fecal microbiota transplantation combined with sintilimab and SOX as first-line treatment for advanced gastric cancer (FMT-JSNO-01): A prospective, multicenter, double-blind, randomized placebo-controlled phase II trial.

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Background: Chemotherapy in combination with immunotherapy has emerged as the first-line(1L) standard of care for gastric cancer (GC) patients(pts); nonetheless, the overall prognosis remains suboptimal. Fecal microbiota transplantation (FMT) holds promise in modulating the patient's gut microbiota and immune milieu, thereby augmenting the efficacy of tumor immunotherapy and enhancing long-term survival outcomes. We propose to integrate FMT into the regimen of chemotherapy plus immunotherapy, aiming to assess its efficacy and safety in pts with advanced GC (NCT06405113). **Methods:** FMT-JSNO-01 is a prospective, multicenter, randomized, double-blind, placebo-controlled phase II trial designed to enroll pts with previously untreated, unresectable advanced gastric or gastroesophageal junction adenocarcinoma (GAC/GEJAC) that is human epidermal growth factor receptor 2 (HER2) negative. The physical status score of Eastern Tumor Collaboration Group (ECOG) was 0-1.The study will be conducted in more than 15 multidisciplinary treatment centers for GC in China.The eligible pts were randomly assigned to arm A and arm B. Using a network random system, subjects are randomly assigned in a 1:1 ratio to the experimental group and control group, and competitive random enrollment is conducted at each center.Pts in arm A received fecal microbiota capsule transplantation combined with sintilimab immunotherapy plus S-1 and oxaliplatin (SOX) chemotherapy, while pts in arm B received placebo combined with sintilimab plus SOX . If there is no progression of the disease after 4-6 cycles of 1L treatment, both arms of pts will enter the 1L maintenance treatment stage: S-1 plus sintilimab, until disease progression, intolerance, or death occurs.The primary endpoint of the study is the 2-year overall survival rate (2-year OS rate), with secondary endpoints including median progression-free survival (mPFS), objective response rate (ORR), incidence of adverse events (AEs), diversity of fecal microbiota, and quality of life (QoL). Additionally, exploratory endpoints will encompass efficacy prediction markers in the gut microbiota and proteomics. This study began recruiting pts in June 2024 and is currently ongoing. Clinical trial information: NCT06405113. Research Sponsor: the 2022 Clinical Research project of Changzhou Medical Center, Nanjing Medical University; CMCC202201; 2022 Changzhou 8th Batch of Science and Technology Project (Applied Basic Research); CJ20220086; 2023 Clinical Research Project of Changzhou Medical Center,Nanjing Medical University; CMCC202307; 2023 Changzhou Health Commission Science and Technology Project; QN202320.