TPS12140 **Poster Session**

Fecal microbiota transplantation (FMT) for opioid-induced constipation (OIC): A prospective, multicenter, single-arm, phase II clinical study.

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Background: Opioids are the cornerstone of cancer pain management. Opioid-Induced Constipation (OIC) is the most common adverse effect of opioid therapy. OIC significantly impairs patients' quality of life and reduces compliance, making it a major factor in inadequate pain control. Recent studies indicate that opioids cause gut microbiota dysbiosis, with gut microbes playing a role in modulating opioid-mediated analgesia and tolerance, including constipation. Currently, fecal microbiota transplantation (FMT) has been shown to be an effective method for adjusting gut flora by introducing various metabolically active bacteria. Therefore, we initiated this study to evaluate the efficacy of FMT in treating OIC. **Methods:** In this multicenter, single-arm exploratory study, 30 cancer patients aged 18-80 years who receive opioid treatment for manageable pain but suffer from persistent constipation are planned for enrollment. Other inclusion criteria include ECOG status 0-2, expected survival $\geq$3 months, having received opioid therapy for at least two weeks, currently stable opioid dosage, manageable pain with NRS $\leq$4, and ability to undergo standard laxative treatment and anticancer therapy. Patients unable to ingest enteric capsules or requiring antibiotics for infections are excluded. Enrolled patients will receive weekly FMT. The treatment will be administered continuously for 4 weeks, with follow-up until constipation reoccurs or one month after the last dose, whichever comes first. The primary endpoint is the improvement of constipation (assessed by BFI scale), while secondary endpoints include cancer pain before and after treatment (evaluated by NRS scale), quality of life (measured by QLQ-C30 scale), nutritional status improvement, and safety. Blood and fecal samples will be collected during the study for efficacy evaluation. The study is currently in the open recruitment phase, with the first patient enrolled in January 2025. Clinical trial information: ChiCTR2500096421. Research Sponsor: None.