

Fecal Microbiota Transplantation (FMT)

- IBD often associated with altered gut microbiome, suggesting that FMT might be therapeutically effective¹
- Patients with IBD who receive FMT for recurrent *C. difficile* infections have also experienced improvement in IBD symptoms²
- FMT has been studied in small randomized trials, with mixed results¹
 - A meta-analysis of 6 double-blind RCTs found significant improvement in both clinical and endoscopic remission and response relative to placebo ($P < 0.05$)³
- Additional clinical data needed to determine whether FMT is a safe and effective treatment for IBD¹

Stem Cell Therapy

- Possible efficacy for both HSCT and MST in UC and CD; data are limited¹
 - Safety issues with donor compatibility for allogeneic therapy
- Darvadstrocel
 - Allogeneic, adipose-derived MST
 - Orphan drug designation³
 - Phase 3 trial: complex perianal fistula and CD²
 - ↑ Rates of clinical remission in darvadstrocel group than placebo group (54% vs 30%, respectively)²
 - 53% of patients who achieved remission at 52 weeks had sustained remission after 165 weeks⁴

HSCT vs MST

HSCT: Removes reactive T-lymphocytes through chemotherapy and replaces them with immune-tolerant lymphocytes

MST: Releases cytokines, chemokines, or growth factors, causing reactive lymphocyte apoptosis and immune regulation

HSCT, hematopoietic stem cell therapy; MST, mesenchymal stem cell.

1. Zhang HM, et al. *Int J Mol Sci*. 2022;23(15):8494; 2. Panés J, et al. *Inflamm Bowel Dis*. 2022;28(11):1737-45; 3. FDA. October 18, 2017. Available at:

<https://www.accessdata.fda.gov/scripts/opdlisting/oodp/detailedIndex.cfm?cfgridkey=373012>. Accessed August 10, 2023; 4. Garcias-Olmos D, et al. *Dis Colon Rectum*. 2022;65(5):713-20.