Study demonstrates safety of microbiota transplant therapy in stem cell transplant and leukemia patients

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Published in the *Journal of Clinical Oncology*, University of Minnesota Medical School researchers led a study that demonstrated the safety of

using microbiota transplant therapy (MTT) in patients with acute myeloid leukemia (AML)—a type of blood cancer—and recipients of hematopoietic cell transplantation (HCT).

Current treatment for patients with AML and who receive HCT includes powerful chemotherapy, which can damage their immune system and intestinal lining. Because of this, patients typically require antibiotics to fight and prevent infections. These antibiotics also kill healthy gut microbes, which may worsen treatment outcomes. The goal of MTT is to restore beneficial microbes in the recipient's gut.

"Microbiota transplants are classified as drugs by the U.S. Food and Drug Administration. However, they truly are an entirely different and new class of drugs, and we need to develop and understand their pharmacology. This requires standardized formulations and figuring out the optimal dosing regimens," said Alexander Khoruts, MD, director of the University of Minnesota Microbiota Therapeutics Program.

In a randomized, double-blind study, the research team compared the outcomes of MTT for two groups: patients with AML and HCT recipients. They used a novel, standardized preparation of donor microbiota called MTP-101C, which is formulated in capsules that are taken orally. After each course of antibiotics, patients received either MTT or a placebo.

The study found the rate of infections was lower in HCT and AML patients that received active MTT relative to the patients that received the placebo. However, the difference did not reach statistical significance.

Overall, the study showed MTT was safe and partially improved the imbalance of gut bacteria in patients who had received HCT or had AML. However, it did not significantly reduce the rate of infections in

these patients.

These results will serve as the basis for a larger follow-up study, which will use a more aggressive MTT protocol with the microbiota compound manufactured by the University of Minnesota Microbiota Therapeutics Program. The program has been the world leader in the development and manufacturing of microbiota-based therapeutics over the past decade.

It is working to develop effective and practical restorative microbiota therapies for multiple clinical indications, some of which include infections with Clostridioides difficile, inflammatory bowel disease and different applications in cancer.

More information: Armin Rashidi et al, Randomized Double-Blind Phase II Trial of Fecal Microbiota Transplantation Versus Placebo in Allogeneic Hematopoietic Cell Transplantation and AML, *Journal of Clinical Oncology* (2023). DOI: 10.1200/JCO.22.02366

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