A placebo-controlled, randomized clinical trial to assess the safety, feasibility, and pharmacokinetics of Microbiota transplant therapy with antibiotic preconditioning and fiber supplementation in patients with pulmonary arterial hypertension

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- ages 18-75 - diagnosis of pulmonary arterial hypertension (PAH) - on stable treatment for PAH for one month prior to enrollment - able to swallow capsules - able to provide blood sample and fecal sample

Exclusion Criteria:

- active inflammatory bowel disease or celiac disease - women who are pregnant or breastfeeding - presence of ileostomy or colostomy - on immunosuppressants (calcineurin inhibitors, prednisone at a dose of 20 mg/day or more, methotrexate, azathioprine, immunosuppressive biologics, JAK inhibitors). - history of solid organ or bone marrow transplant - anticipated recurrent antibiotic use (patients with frequent urinary tract infections or sinusitis) - history of severe anaphylactic food allergy - receiving cancer chemotherapy, immunotherapy, or radiation

Conditions & Interventions

Interventions:
Drug: MTT with antibiotic preconditioning + fiber supplementation, Drug: MTT with antibiotic preconditioning + placebo supplementation, Other: MTT with placebo + placebo supplementation.
Conditions:
Heart & Vascular, Microbiota
Keywords:
Microbiota transplant therapy, PAH, pulmonary arterial hypertension, Clinics and Surgery Center (CSC), gut

More Information

Description: There is evidence that the gut microbes interact with the body's immune system, and people with pulmonary hypertension may have altered composition of gut microbes. We are studying whether transplanting gut microbes from healthy donors using a treatment called microbiota transplant therapy may have beneficial effects on pulmonary arterial hypertension.
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Phase: PHASE1
IRB Number: STUDY00022382

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