

An Open-Label, Pilot Clinical Trial To Test The Safety And Feasibility Of Intestinal Microbiota Transplantation In Patients With Pulmonary Arterial Hypertension

Status: Recruiting

Eligibility Criteria

Sex: All

Age: 18 Years to 75 Years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 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:

- Dysphagia to pills
- Clinically active inflammatory bowel disease
- Pregnancy or breastfeeding
- Life expectancy of <6 months
- Presence of ileostomy or colostomy
- Taking immunosuppressants (calcineurin inhibitors, prednisone greater than or equal to 20mg/day, methotrexate, azathioprine, immunosuppressive biologics, JAK inhibitors)
- Neurotopenia (an absolute neutrophil count < 0.5×10^9 cells/L)
- History of solid organ or bone marrow transplant
- Anticipated recurrent antibiotic use (participants with frequent urinary tract infections or sinusitis)
- History of severe anaphylactic food allergy
- History of celiac disease
- History of receiving cancer chemotherapy, immunotherapy, or radiation

Conditions & Interventions

Interventions:

Drug: Intestinal microbiota transplant (IMT)

Conditions:

Pulmonary Arterial Hypertension

More Information

Description: This pilot clinical trial will evaluate the initial safety and feasibility of intestinal microbiota transplantation (IMT) in patients with pulmonary arterial hypertension (PAH). This trial will inform development of future trials in treatment of PAH. Active drug in capsule form composed of freeze-dried, encapsulated intestinal microbiota from healthy donors will be administered to patients with PAH. This study will also allow for limited evaluation of pharmacokinetics in terms of donor microbiota engraftment and pharmacodynamics in terms of potential mechanisms. It will also allow for limited evaluation of cardiac endurance and function prior to and after IMT.

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