Intestinal Microbiota Transplant in Alcohol-Associated Liver Disease

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

-\>18 years of age * Advanced liver disease * Able to give written, informed consent * Alcohol as a cause of advanced liver disease * Continued sustained drinking * Having previously declined a referral to traditional AUD therapy services or having failed such treatments

Exclusion Criteria:

* Lack of sustained drinking * Recent or current alcoholic hepatitis * Alcohol withdrawal symptoms * Clinically significant use of illicit drugs * Uncontrolled mood disorders or primary psychotic conditions * MELD score\>17 * Unclear diagnosis of chronic liver disease * Current hepatic encephalopathy on lactulose and/or rifaximin * WBC count\<1000 * Non-elective hospitalization within last month * on dialysis * known untreated, in-situ luminal GI cancers * chronic intrinsic GI diseases (ulcerative colitis, Crohn's disease or microscopic colitis, eosinophilic gastroenteritis and celiac disease) * Dysphagia within 2 weeks * History of aspiration, gastroparesis, intestinal obstruction * Ongoing absorbable antibiotic use * Severe anaphylactic food allergy * allergy to ingredients Generally Recognized As Safe in the G3 capsules (glycerol, sodium chloride, hypromellose, gellan gum, titanium dioxide, theobroma oil) * Adverse event attributable to prior IMT * ASA Class IV or V * Pregnant or nursing patients * acute illness or fever on the day of planned FMT * Immunosuppression * Other conditions which make patients are poor candidate for this study per investigator judgement

Conditions & Interventions

Interventions:

DRUG: Intestinal Microbiota Transplant (IMT) Capsules, DRUG: Placebo Capsules

Conditions:

Liver Disease, Alcohol-Related, Cirrhosis, Alcohol Use Disorder

Keywords:

Intestinal Microbiota Transplant, Alcohol Use Disorder, Cirrhosis, Chronic Liver Disease

More Information

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Principal Investigator: Phase: PHASE1

IRB Number:

System ID: NCT05548452

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