

Efficacy, Safety, And Pharmacokinetics Of Rifaximin In Subjects With Severe Hepatic Impairment And Hepatic Encephalopathy

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- Male or non-pregnant, non-breast feeding female \geq 18 years old
- In remission from demonstrated overt HE
- Had \geq 1 episode of overt HE associated with liver disease within the last 6 months
- MELD score of \geq 19
- Has a close family member or other personal contact who is familiar with the subject's HE, can provide continuing oversight to the subject and is willing to be available to the subject during the conduct of the trial

Exclusion Criteria:

- HIV
- History of tuberculosis infection
- Chronic respiratory insufficiency
- Current infection and receiving antibiotics
- Renal insufficiency requiring dialysis
- Active spontaneous bacterial peritonitis infection
- Intestinal obstruction or has inflammatory bowel disease
- Active malignancy within the last 5 years
- Current GI bleeding or has had a GI hemorrhage within past 3 months
- Anemia

Conditions & Interventions

Interventions:

Drug: Placebo, Drug: Rifaximin

Conditions:

Hepatic Encephalopathy

Keywords:

Hepatic Encephalopathy, Liver Failure, Hepatic Insufficiency, Liver Diseases, Brain Diseases, Rifaximin, Cirrhosis

More Information

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Principal Investigator:

Phase: Phase 4

IRB

Number:

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