

Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of EP547 in Subjects with Cholestatic Pruritus Due to Primary Biliary Cholangitis or Primary Sclerosing Cholangitis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. diagnosed with primary biliary cholangitis (PBC) or primary sclerosing cholangitis (PSC 2. consistent moderate to severe pruritus (itching)

Exclusion Criteria:

1. prior or planned liver transplantation 2. liver cirrhosis 3. significant small bowel resection or short bowel syndrome

Conditions & Interventions

Conditions:

Dermatology (Skin, Hair & Nails), Digestive & Liver Health

Keywords:

Clinics and Surgery Center (CSC), Itching, Pruritus

More Information

Description: The purpose of this study is to find out the safety and tolerability (the degree to which side effects affect a participant's willingness to continue taking study drug) of the study drug EP547 in patients with itch associated with cholestatic liver disease and to determine the amount of EP547 in the blood after dosing. EP547 is an experimental drug that is not approved by the Food and Drug Administration (FDA) for the treatment of itch associated with liver disease or of any other conditions. This study will have 9 study visits which includes a screening period of up to 4 weeks long, a 12-week treatment period, and a follow-up visit 2 weeks after stopping study treatment.

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