A 52-week, Double-blind, Placebo-controlled, Randomized, Phase 3 study Intended to Determine the Effects of seladelpar on normalization of Alkaline phosphatase Levels in Subjects with Primary Biliary Cholangitis (PBC) and an Incomplete Response or Intolerance to Ursodeoxycholic Acid (UDCA)

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- 18 to 75 years old - taking Ursodeoxycholic Acid (UDCA) for 12 months prior to screening (with stable dose for more than 3 months before starting the study) OR unable to take UDCA (last dose of UDCA greater than 3 months before starting the study) - study staff will review additional inclusion and exclusion criteria

Exclusion Criteria:

- other chronic liver diseases - drinking more than 2 drinks per day in women and 3 drinks per day in men, or unable to quantify alcohol intake reliably - history of cancer diagnosed or treated, active or within 2 years, or ongoing evaluation for cancer; squamous or noninvasive basal cell skin cancers and cervical carcinoma in situ are allowed (if treated) - women who are pregnant or plan to become pregnant, or are breastfeeding

Conditions & Interventions

Conditions:
Digestive & Liver Health
Keywords:
Clinics and Surgery Center (CSC), Primary Biliary Cholangitis

More Information

Description: The purpose of this research study is to determine if seladelpar (study drug) is effective at normalizing the disease marker alkaline phosphatase in subjects with PBC who are currently on ursodeoxycholic acid (UDCA) treatment or intolerant to UDCA. This will be done by looking at changes in blood tests. This research study is also measuring whether seladelpar makes itching (pruritus) better. This will be done using information about itching that subjects enter on a device or app on their phone.
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