

The PACIFIC study is currently enrolling participants with itch (pruritus) associated with cholestatic liver diseases such as Primary Biliary Cholangitis (PBC) or Primary Sclerosing Cholangitis (PSC).

To take part, you must:

- Be 18-80 years old
- Have a diagnosis of PBC or PSC
- Be experiencing moderate to severe itch related to cholestatic liver disease

For more information, please contact:

PACIFICitchstudy.com



There are no approved treatment options available for the itch caused by PBC and PSC. This study may lead to the development of a new treatment.

About the study drug

How itch occurs in patients with liver disease is not fully understood. However, when the liver isn't working properly, researchers believe that chemicals can build up in the skin, where they may activate a receptor that causes itch. EP547 is a new investigational treatment designed to block the receptor that causes itch. EP547 is not intended to improve the liver disease associated with PBC or PSC, but rather to help reduce the itch that liver disease can cause. EP547 is an investigational drug, which means it is not approved by any health authorities and is only available through participation in a clinical study like the PACIFIC study.



What is involved in the PACIFIC study?

About 62 people will take part in this study at multiple study sites globally. Study participation lasts about 4 months and is divided into 4 main periods:



• **Screening (2 to 4 weeks):** Your medical history will be reviewed and tests will be done at the study visit to see if you qualify. You will be asked to rate your itch daily during this period and throughout the study.



• **Double-Blind Dosing (approximately 6 weeks):** If you qualify, you will be randomly assigned to study treatment with a 50/50 chance of getting either EP547 (the investigational drug) or placebo (an inactive substance). Neither you nor your study doctor will know which treatment you have been assigned (double-blind). You will have 5 study visits during this time for study tests and health checks.



• **Open-Label Dosing (approximately 6 weeks):** After completion of the double-blind dosing period, all participants will receive EP547 and will attend 2 more study visits during this period. This period is considered 'open-label,' which means that you and the study doctor will know which treatment you are receiving.



• Follow-up (2 weeks): Two weeks after your last dose of study drug, you will be asked to return to the study site for a final visit so the study doctor can check on your health.

Will the PACIFIC study cost me anything?

If you decide to participate, study treatment, visits, tests and procedures that are needed in this study will be provided at no cost to you. The study staff can tell you about any reimbursement for travel-related expenses or compensation that may be available.

Please speak to your healthcare team, family, and study staff to help decide if the PACIFIC study may be right for you.

