What are clinical research studies?

Clinical research studies help scientists and doctors explore whether a drug is safe and whether it works. Before a doctor can prescribe a new drug, it must go through several phases of clinical research. Clinical research is only possible with the help of volunteers who participate in research studies. Participation is a choice, and volunteers may stop participating at any time.

Why join a clinical research study?

Finding a therapy that works for your primary biliary cholangitis (PBC) when others have not can be frustrating, but it is important to your overall health. PBC is a rare, chronic disease that damages cells in the liver. The body mistakenly attacks its own healthy cells, which causes slow destruction of the bile ducts in the liver from buildup of toxic bile acids. The goal of the IDEAL study is to research how the study drug, seladelpar, works in adults with primary biliary cholangitis (PBC) with the hope of offering better options in the future.

For more information about the IDEAL study, visit idealpbcstudy.com or contact:

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CYMABAY

Discover a new option for primary biliary cholangitis

Consider joining the IDEAL study.

IDEAL

What is the IDEAL study?

The IDEAL study is exploring a study drug that may decrease unpleasant symptoms, may lead to improvements in the laboratory tests that measure the function of the liver, and has potential to improve quality of life in people with PBC. Ursodeoxycholic acid (UDCA) is the main approved option for PBC, but it does not work for everyone. This study is evaluating a possible new option for people who have not achieved a full response to UDCA.

The IDEAL study will last up to 58 weeks and include the following periods:

- **Screening:** Up to 4 weeks
  - Confirm that you are eligible to participate in the study
  - Sign the Informed Consent Form before receiving any health assessments
  - Be randomly assigned to the placebo or active study drug group
- **Dosing Period:** Up to 52 weeks (1 year)
  - Take the assigned active study drug or placebo once daily
  - Visit the study clinic about 6 times for health assessments
- **Follow-up:** 2 weeks
  - Visit the study clinic for final health assessments
  - Complete Follow-up even if you leave the trial early

What is the study drug?

- Designed to decrease the production of bile acids and reduce inflammation in the liver
- A capsule taken by mouth once daily
- Matching placebo will be given to some randomly selected participants. The placebo will look like the active study drug but is made with no active ingredients

Why is placebo being used?

- In many clinical trials with placebo, neither the participant nor the study doctor knows who is receiving the study drug and who is receiving placebo. Having a separate group that does not receive any active ingredients helps the study doctor see if an experimental drug is truly effective or not
- Placebos play a big part in advancing research and improving the lives of others in the future
- It's important to remember that placebos would not be used in a clinical trial if it would put participants at risk

Who can join the study?

You may be eligible to participate if you meet the following criteria*:

- Are 18 to 75 years old (inclusive)
- Diagnosed with PBC
- Have taken UDCA for the 12 months prior to screening (with stable dose for >3 months prior to Screening) OR are intolerant to UDCA (last dose of UDCA >3 months prior to Screening)
- Have **NOT** taken seladelpar in the past

*Additional criteria apply.