What is the AFFIRM study about?

A clinical research study is conducted to learn if a new drug, vaccine, booster, treatment, or method is safe and effective. Research personnel conduct a pre-planned set of tests and follow strict scientific standards and regulations to protect participants and to ensure the study produces accurate information for health care decision making.

In this study, doctors are trying to learn more about the effectiveness and safety of an investigational drug called seladelpar for patients with primary biliary cholangitis (PBC). If you have PBC, which used to be called primary biliary cirrhosis, you may qualify for the AFFIRM clinical research study.

AFFIRM

A Study for Primary Biliary Cholangitis Treatment

Those who qualify may receive:

- No-cost study-related care from local doctors and specialists
- No-cost study medication

Contact us to learn more:

[URL]
[TELEPHONE]
[EMAIL]
[CONTACT INFO]

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Managing Your PBC Is a Challenge

Your participation in primary biliary cholangitis (PBC) clinical research could help advance medical science for PBC.

AFFIRM

A Study for Primary Biliary Cholangitis Treatment

Study overview

- Any adult age 18 to 75 with a confirmed diagnosis of PBC who meet the inclusion criteria may be eligible to join the study
- AFFIRM is studying the effect of seladelpar on clinical outcomes in patients with primary biliary cholangitis (PBC) and compensated cirrhosis
- Participation may be allowed whether or not currently on UDCA therapy
- The study includes a screening period of up to 5-weeks, a 156-week treatment period, and a 2-week safety follow-up period

IMPORTANT! If you join AFFIRM, you may withdraw from the study at any time, for any reason. Participation is completely up to you.

Why are doctors studying PBC in this study?

PBC is a chronic autoimmune liver disease that affects the way the liver functions. Doctors usually prescribe UDCA to help manage PBC, but it works better for some people than for others. In this study, we want to assess the effect of seladelpar on clinical outcomes.

Important information about this study

To qualify for this study, you must:

- Be an adult age 18-75
- Have been diagnosed with PBC
- Have a diagnosis of compensated cirrhosis with a Child-Pugh Score A or B

Doctors will check other requirements to confirm that you qualify for this study. There is no guarantee that being treated with seladelpar will have any effect on your PBC.

There is a 1 in 3 chance you will receive a placebo in this study. Placebo is an inactive substance that looks like the investigational drug. During the study, you will not know if you are receiving placebo or seladelpar.

Why should I participate in this study?

First and foremost, your participation in the AFFIRM study could help advance medical science and may eventually lead to expanded treatment options for people with PBC.

If you qualify for and participate in this study, you may receive the following:

- Study-related medications
- Study-related care from a PBC expert
- Study-related medical tests

All study medication and study-related care will be at no cost to you. Talk to your doctor about screening to see if you are eligible.

What happens if I volunteer?

After you volunteer, the study doctor and staff will give you some tests to make sure you qualify. This is called the “screening period,” and it could take up to 5 weeks to confirm your eligibility.

If you qualify and choose to participate, you will take the study drug or placebo daily and participate in regularly scheduled clinic visits until the study ends.

During the study (about 156 weeks), you will visit the clinic on Day 1, weeks 2, 4, 8, 12, and 26, then every 13 weeks thereafter until week 156, which will conclude your study treatment period. You will also have a follow-up visit after you leave the study two weeks to 17 days after that.

Your participation is your choice.
Talk to your doctor and family to decide if this study is right for you.