
Do you have cardiovascular disease and elevated cholesterol levels?
Learn more about the PREVAIL study!
Learn more about the study
PREVAIL is a clinical trial designed to determine whether an investigational new drug, obicetrapib, can reduce the risk of cardiovascular events (like a heart attack or stroke) in individuals with Atherosclerotic Cardiovascular Disease (ASCVD).
See if You Qualify
Find and contact a study center near you
Study Center Locations
Study Information
Join the Study
Resources

Navigation Page One – About the Study & Therapy

PREVAIL

About the Study & Therapy | ASCVD & Elevated Cholesterol | PREVAIL Academic Leadership | About Clinical Trials | See if You Qualify | Find a Study Center Near You

About the Study and the Study Therapy

What is the purpose of the PREVAIL study?

The PREVAIL trial is being conducted to determine whether an investigational new drug, previously shown to reduce circulating levels of low-density lipoprotein cholesterol, can also reduce the risk of cardiovascular events (like a heart attack or stroke) in individuals who have atherosclerotic cardiovascular disease (ASCVD).

ASCVD disease refers to the accumulation of fat-laden plaque just beneath the lining of the heart blood vessels known as coronary artery disease (CAD), the blood vessels supplying blood to the legs known as peripheral arterial disease (PAD), and/or vessels supplying blood to the brain known as cerebrovascular disease.

The clinical manifestations of this disease process include angina (pain in the chest), heart attack, stroke, leg claudication (pain in the leg) and ultimately severe debilitation or even death.

What is the study drug?

The study drug, obicetrapib 10 mg, is a small tablet taken by mouth once a day. It is designed to reduce cholesterol levels, specifically low-density lipoprotein cholesterol (LDL-C), which is a harmful form of cholesterol. LDL-C can cause fatty buildup in the arteries, which narrows the arteries and increases the risk of cardiovascular disease. It's mechanism of action results in a reduction of high LDL-C levels.

Obicetrapib is an **investigational drug**, which means it can only be used for research studies. It has not been approved by regulatory authorities like the Food and Drug Administration (FDA) or European Medicines Agency (EMA).

What will happen during the study?

Before receiving any study drug or study related assessments, your eligibility for participation and consent to participate are required. You will need to satisfy specific inclusion and exclusion criteria to enroll into the study.

Once you consent to participate in the trial during the Screening Visit, you will then attend 4 further visits (Months 0, 3, 6, 12) during the first year, followed by visits every 6 months for the remainder of the study. Between visits at the study center, you will have telephone visits to see how you are feeling.

As this is an event-driven study (meaning that the study will last until a certain number of cardiovascular events happen in the study participants), the actual study duration may vary. We anticipate that participants can expect to be in the study for about 3-4 years.

Navigation Page One – About the Study & Therapy (continued)

What will happen during the study?

Before receiving any study drug or study related assessments, your eligibility for participation and consent to participate are required. You will need to satisfy specific inclusion and exclusion criteria to enroll into the study.

Once you consent to participate in the trial during the Screening Visit, you will then attend 4 further visits (Months 0, 3, 6, 12) during the first year, followed by visits every 6 months for the remainder of the study. Between visits at the study center, you will have telephone visits to see how you are feeling.

As this is an event-driven study (meaning that the study will last until a certain number of cardiovascular events happen in the study participants), the actual study duration may vary. We anticipate that participants can expect to be in the study for about 3-4 years.

Participation includes:

- Study clinic visits with physical exams, blood tests, and the assessment of possible experienced cardiovascular events
- Assigned at random (like a coin flip) to receive either the study drug obicetrapib or placebo (which contains no active ingredients), with 50% (1 in 2) chance of receiving study drug
    - Assigned study drug (or placebo) to be taken by mouth once a day with water at around the same time each day
    - Neither you or your investigating physician will know which tablet (study drug or placebo) you are taking
- Follow-up telephone visit after the last dose of the assigned study drug or placebo
- Continue taking pre-existing medication to lower cholesterol that has been regularly prescribed by your general practitioner/family physician (if applicable)

Navigation Page Two – ASCVD & Elevated Cholesterol