What are clinical research studies?

Clinical research studies help scientists and doctors explore if new medical strategies or drugs are safe and effective for people. They have 4 phases:

- Phase 1: First study of the drug in people (often healthy volunteers)
- Phase 2: Study of the drug in people with the condition the drug is designed to improve
- Phase 3: Study confirming how effective the drug is for improving the condition
- Phase 4: Continued research after the drug is approved for public use

PREVAIL is a Phase 3 study. Participation in clinical research studies is your choice, and you may withdraw from the study at any time. We appreciate and thank you for considering the PREVAIL study.

For more information about the PREVAIL study, contact:

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Do you have cardiovascular disease and elevated cholesterol levels?

Ask to see if you qualify to participate in the PREVAIL study.

PREVAIL

What is the PREVAIL study?

PREVAIL is a clinical research study evaluating the safety and effectiveness of an investigational drug in people who have cardiovascular disease. Cardiovascular disease can involve blood vessels to the heart known as coronary artery disease (CAD), blood vessels to the legs known as peripheral arterial disease (PAD), and/or blood vessels to the brain (cerebrovascular disease). Some related health issues include heart attacks and strokes.

What is the study medication?

The investigational study drug, obicetrapib, is designed to lower cholesterol, specifically low-density lipoprotein cholesterol (LDL-C). LDL-C is known to be a harmful or "bad" form of cholesterol because it can cause fatty buildup in your arteries, which narrows the arteries and increases the risk of cardiovascular disease. The study drug targets a specific protein to possibly reduce LDL-C levels and increase high-density lipoprotein cholesterol (HDL-C) levels, a form of "good" cholesterol.

Investigational means the study drug has not been approved for public use by regulatory authorities and can only be used in research studies.

Who can join the study?

You may qualify if you meet the following requirements*:

- 18 years of age or older
- Have a history of cardiovascular disease
- Have elevated cholesterol levels:
  - Fasting LDL-C of 100 mg/dL (2.6 mmol/L) or greater

    OR
  - Fasting LDL-C of 55 mg/dL (1.4 mmol/L) to 100 mg/dL (2.6 mmol/L) with at least 1 of the following risk factors:
    - Recent heart attack (about 3 months ago to less than 1 year);
    - Type 2 diabetes;
    - Other blood test results such as fasting triglycerides greater than 150 mg/dL (1.7 mmol/L), or fasting HDL-C less than 40 mg/dL (1.0 mmol/L)
- Taking medication(s) to lower cholesterol (if applicable). Examples of medications include:
  - Statins such as atorvastatin (Lipitor®) and rosuvastatin (Crestor®) with a maximum dose that you can tolerate
  - Ezetimibe (Zetia®) or bempedoic acid (Nexletol®)
  - PCSK9-targeted therapies (such as Repatha® or Praluent®)

*Additional requirements will apply.

What can study participants expect?

For those who qualify, participation lasts for about 3 to 4 years. Participation includes:

- Attend study clinic visits with assessments such as physical exams and blood tests, and telephone visits
  - **Note:** fasting is required for at least 8 hours before study clinic visits
- Be assigned at random (like a coin flip) to receive either the study drug or placebo (no active ingredients)
  - Have 50% (1 in 2) chance of receiving study drug
  - Assigned study drug or placebo taken by mouth once daily
- Continue taking medication to lower cholesterol that has been prescribed by your general practitioner (if applicable)
- Follow a cholesterol-lowering diet and make lifestyle changes as instructed by your general practitioner
- Have a follow-up visit after the last dose of the assigned study drug or placebo (via telephone)

PREVAIL