

Hepatitis B Clinical Trials

What You Need To Know

There are promising new drugs that are being tested for hepatitis B treatment in the U.S. and around the world. In the U.S., before any drug is approved for general use by the **Food and Drug Administration (FDA)**, the drug must go through three phases of testing that involve studies called *clinical trials*. People volunteer to participate in these trials, and all potential study participants are carefully screened. Participants must meet strict criteria before being accepted into a study and must sign informed consent forms.

U.S. Food and Drug Administration (FDA): This is a federal organization charged with protecting the public's health. The FDA establishes safety and effectiveness guidelines for healthcare products such as the drugs that are used to treat hepatitis B.

What is a clinical trial?

Clinical trials are carefully controlled studies that are used to determine whether new drugs, treatments, or medical products are safe and effective. Clinical trials can be funded through pharmaceutical companies, the National Institutes of Health (NIH) or other funding sources. Clinical trials are conducted at universities, doctors' offices and hospital clinics. All drugs in the U.S. undergo three phases of clinical trials before being approved for general use. Once a drug is approved and used by the general public, a Phase IV study examines possible long-term effects.

- **Phase I:** Drugs are tested in a few volunteers (20-100) to evaluate safety, determine safe dosage levels and identify side effects. These trials may last several months.
- **Phase II:** Drugs have passed Phase I and are tested in more people (100-500) to further evaluate safety and effectiveness. Phase II trials may last several months to 2 years.
- **Phase III:** Drugs are tested in a large number of people (1,000-5,000) to confirm long-term effectiveness, monitor side effects and compare with commonly used treatments. Phase III trials may last several years.
- **Phase IV:** Performed after a drug has been approved to collect information about its effects in various populations, including possible long-term side effects.

Why would someone choose to participate in a clinical trial?

There are several advantages to participating in clinical trials. Expensive blood work, treatment medications and clinical monitoring may be provided free of charge. Clinical trials provide patients the opportunity to potentially benefit from the very latest advances in medical science.

How are volunteers who participate in clinical trials protected?

The government has strict guidelines to protect people who choose to participate in clinical trials. Each clinical trial is approved and monitored by an Institutional Review Board (IRB) of the organization conducting the clinical trial. The IRB includes physicians, ethicists, community health advocates and others to ensure that the risks are as low as possible and are worthy of the potential benefits.



The Hepatitis B Foundation is a national nonprofit organization dedicated to finding a cure and improving the quality of life for those affected by hepatitis B worldwide.

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What is informed consent?

Anyone participating in a clinical trial is required to read and sign an informed consent form. This form provides detailed information about how the study will be conducted, what kind of medical care the patient can expect during and after the study and the possible risks and benefits. A patient may choose to leave a study at any time.

What should you know before you join a clinical trial?

Before you join a trial, you should know as much as possible about the study. It is important to fully understand the details of a clinical trial, the potential risks and benefits and what will be expected of you during the study. You should be comfortable asking questions and having the medical staff answer them in a way that you can understand.

Tips for learning about clinical trials:

- Ask your primary care provider or specialist what clinical trials are available for you.
- Search reliable websites for information about existing clinical trials or drugs currently in development that may soon be recruiting for clinical trial participants.
- Enlist your doctor to help you sift through all the information and review the pros and cons.
- Take a friend or family member with you when you meet the medical staff to discuss the study.

The Hepatitis B Foundation provides a clinical trials guide on its website at www.hepb.org/clinicaltrials. This guide helps you easily navigate the [National Institutes of Health \(NIH\)](http://www.clinicaltrials.gov) clinical trials database so you can find trials that are best for you. The NIH clinical trials website can be found at site at www.clinicaltrials.gov.

Questions to ask your doctor about clinical trials:

- What clinical trials are available for HBV, and which ones might be right for me?
- How long will the trial last, where is it being conducted, and how often will I need to go there?
- Why do researchers think the new drug will work better than other approved treatments?
- Who is most likely to benefit from this drug and what criteria may be associated with success?
- How many people have tested the drug and what has happened to them?
- What will be expected of me throughout the trial (what tests or medical procedures will I need)?
- What are the possible risks and side effects involved?
- What are the possible long- and short-term benefits?
- Is taking the trial drug riskier than taking no treatment or continuing existing treatment?
- Do I have to pay for any part of the trial or will my insurance pay for it?
- What happens to my HBV when I stop taking the drug?
- What is the medical follow-up care after the trial ends?
- If this drug doesn't work for me, am I eligible to participate in another trial?

How can I learn more about specific clinical trials for hepatitis B?

- First, talk to your doctor. If he or she is unfamiliar with clinical trials for HBV, then find a liver specialist (or "hepatologist") at the largest teaching hospital in your area.
- Visit the [Hepatitis B Foundation](http://www.hepb.org) website for a directory of liver specialists, the HBV Clinical trials guide and an updated HBV Drug Watch at www.hepb.org.



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