

Hepatitis B Fact Sheet

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a series of fact sheets written by experts in the field of liver disease



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How to Evaluate a Clinical Trial

After a new drug is tested in laboratory settings and shows promise, it is tested on humans in a clinical trial. Today, there are dozens of clinical trials or studies that evaluate new antivirals, interferons, and innovative vaccines on patients infected with the hepatitis B virus (HBV).

Researchers recruit patients through the U.S. National Institutes of Health's Clinicaltrials.gov registry, Centerwatch.com, and through medical offices and organizations. Doctors learn about the trials and may suggest a trial to a patient who meets the study's criteria. Specialists (hepatologists or gastroenterologists) participating in or leading the study may recruit their own patients. Even when doctors are not directly involved in a trial, they can refer patients and may perform testing and monitoring required by the trial and then send the results to the study's researcher.

Patients should be guaranteed that, if they end up in the placebo group, they will have access to the new drug, if it proves successful, at the end of the trial

Every clinical trial in the United States must be approved and monitored by the researcher's Institutional Review Board (IRB) to make sure the risks to patients are as low as possible. Every participant is asked to read, understand and sign a consent form that lists the potential dangers or risks. Patients must ask many questions and make sure they could benefit from the experimental treatment before enrolling.

Questions patients should ask before enrolling:

- Why is this drug potentially better than what is currently approved for hepatitis B treatment by the U.S. Food and Drug Administration?
- Has it been used successfully on other viral infections, such as HIV?
- What are the possible risks, side effects, and benefits?
- If the drug is an antiviral, will it cause viral resistance or cross-resistance?
- How will the treatment affect quality of life?
- Will researchers cover the cost of the drug and doctor's visits?
- What follow-up care is required?
- What determines if the drug was successful?



Clinical Trials

- Will results of the trial be provided to participants?
- Will a specialist or a primary care provider be in charge of a patient's care?
- Is there a chance a patient could get a placebo instead of the experimental drug?

Getting support:

When patients meet with a study's doctor or coordinator, it is important to plan ahead and write down questions to ask to evaluate the study. Ask a friend or relative to come along to hear the doctor's responses, and tape record the discussion to review later. If the patient is young, bring a babysitter so parents/caregivers can speak privately, without distractions, with the doctor.

Randomized trials risks and benefits:

Participating in a randomized trial means some patients will receive a placebo (a sugar pill that provides no treatment), some will get the current conventional treatment for hepatitis B, and some will get the new, experimental drug. Before par-

ticipating in a clinical trial, patients should be guaranteed that, if they end up in the placebo group, they will have access to the new drug, if it proves successful, at the end of the trial.

Helpful websites about clinical trials:

- **www.clinicaltrials.gov** features information about hepatitis B clinical trials in the U.S. and around the world.
- **www.centerwatch.com** provides clinical trials information to professionals and patients through its online database and email lists.

Different Phases of a Clinical Trial

Phase I: This is the first time a drug is tried in humans. The goals are to discover if the drug works, the safety of the drug, and what quantity can be given safely.

Phase II: The drug appears promising, so now researchers will try to fine-tune its dose and evaluate its safety and effectiveness.

Phase III: The drug is compared to the current standard of treatment to see if it is superior or as effective. During this phase, patients will often be treated with either the new drug, the current standard drug that is the standard of care, or a placebo.

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The information in this fact sheet is designed to help you understand and manage HBV and is not intended as medical advice. All persons with HBV should consult a medical practitioner for diagnosis and treatment of HBV.

For more information about hepatitis B, visit the following websites.
Hepatitis B Foundation: www.hepb.org • HIVandHepatitis.com

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