

Hepatitis C

Clinical Trials and Hepatitis C Treatment

You may wonder how you can get treatment for your hepatitis C virus infection. One thing you can do is to enroll in a clinical trial. This handout answers some questions about clinical trials and may help you decide if joining one is a good idea for you.

What is a clinical trial?

A clinical trial is a research program that tests a new medicine to see if it is safe and works well. When a new medicine (or *drug*) is first discovered, you cannot get it by prescription. Researchers must first test it in a laboratory with animals. Then, they must do a clinical trial in a hospital or clinic to test it in people. They test it to see if it is safe and to see how much of the medicine (or *what dose*) is enough to work.

The Food and Drug Administration (FDA) is a government agency that decides if a new drug is safe enough to give to patients by prescription. It looks at the results of the clinical trials to make this decision. Testing drugs for hepatitis C is very important, and clinical trials are a way to find new and better medicines. All medicines that you can now get for hepatitis C were first tested in clinical trials.

How do clinical trials work?

Clinical trials follow a set of rules called a *protocol*. The protocol says who can participate, how long the study is, and which tests need to be done.

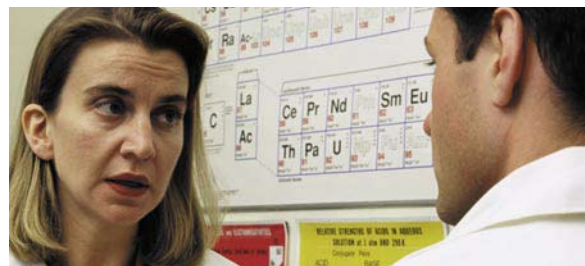
Clinical trials are managed by doctors and are usually run by nurses or other health care professionals. The clinical trial staff will follow your progress closely and can help tell your regular doctor what is happening with your treatment.

Trials are also checked by an institutional review board (IRB). This is a group of people who reviews the clinical trial regularly to protect your rights, safety, and well-being.

When you are in a clinical trial, you may need to see the doctor more often and sometimes stay overnight in the hospital. This is because they want to check the effects of the medicine carefully. Because clinical trials are research, they will often test the real drug against a placebo (or *sugar pill*). Usually you will not know if you are taking the medicine or the placebo until the clinical trial is over.

How do I begin a clinical trial?

Before you start a clinical trial, you will go through a screening process. This is to make sure that it is safe for you to start taking the medicine. The staff will ask you about your health history, and you may have a blood test, urine test, or others (such as a *physical exam* or a *heart test*).



What is informed consent?

You will also go through a process called *informed consent*. The doctors and nurses will explain exactly what will happen during the clinical trial. They will answer your questions and tell you about the risks and benefits of the clinical trial. They will ask you to sign a document called a

consent form. When you sign this form, you are saying that you understand what is going to happen and that you agree to participate. Even after you have started a clinical trial, you are free to quit at any time for any reason. Quitting early will not affect your medical care in the future.

What are the different types of clinical trials?

There are four different types of clinical trials: Phase I, Phase II, Phase III, and Phase IV.

<i>Phase I</i>	<i>Phase II</i>	<i>Phase III</i>	<i>Phase IV</i>
<ul style="list-style-type: none"> ● is the first time they have tried the drug in people ● tests for the drug's safety and helps find the right dose ● may ask for frequent tests or a stay in the hospital to check for safety and effectiveness ● lasts a fairly short time ● has a small number of patient volunteers 	<ul style="list-style-type: none"> ● happens when early studies show that the drug may work well to fight hepatitis C ● tests for safety and effective dose level ● lasts longer than Phase I trials ● tries to find out what kind of side effects you get with this medicine ● has several hundred patients 	<ul style="list-style-type: none"> ● happens if the drug worked well in Phase I and II ● compares standard treatments (<i>medicines that you can already get by prescription</i>) or sugar pills (<i>placebos</i>) with the new medicine ● may last longer than Phases I and II ● looks for ways to reduce the side effects and improve the quality of your life while you are taking the medicine ● is the last phase of study before a drug is sent to the FDA ● has many patients (<i>sometimes thousands</i>) 	<ul style="list-style-type: none"> ● happens when the drug is already available by prescription ● happens less often than other phases ● checks other safety issues and long-term side effects ● may be used to check higher or lower amounts (or <i>doses</i>) of the medicine

Does it cost anything to participate in a clinical trial?

No. It will not cost you anything because you are helping the researchers to test a new medicine. Sometimes you may even get extra money to pay for your time or travel.

How long do clinical trials last?

Clinical trials can last from a few weeks to several months. After the treatment is over, they will usually ask you to come back for some follow-up visits. The follow-up period may be as short as a few weeks or as long as six months and helps to make sure that you are safe.

How long does it take for a medication to be approved by the FDA?

It usually takes about 10 years for a drug to be developed and approved for prescription. Many people would like to take the newest medicine as soon as it is proven to work. However, even after a drug has been successful in a Phase III trial, it still may take six to 12 months before that drug is approved for prescription.



What are the benefits and risks of being in a clinical trial?

Before you start a clinical trial, you should think about the positive and negative things that may happen.

Benefits:

- You may get frequent free checkups from hepatitis C specialists.
- You can get free medicine.
- You can get new medicine that is not yet available from your regular doctor and may work better than the old medicine.
- You may learn a lot about your hepatitis C disease and how to take care of yourself.
- You may help medical researchers to find better treatments for all patients with hepatitis C.

Risks:

- You may have side effects from the medicine that you did not expect.
- You may have to have frequent office visits, blood tests, and other medical exams.
- You may not get better from the treatment.

Who pays for clinical trials?

Trials are paid for by government agencies, pharmaceutical (or *drug*) companies, individual doctors and hospitals, or clinics. Most hepatitis C clinical trials are paid for by the companies that make the drugs. The doctors and nurses will tell you who is paying for the study before you begin a trial.

If I want to be in a clinical trial, will I definitely be able to participate?

Not necessarily. Most clinical trials have *eligibility criteria*. These are rules about who can participate, based on health, age, and maybe other things. They are designed to keep you safe and to help you get the best results. If you do not meet these criteria, you will probably not be able to participate. If you do qualify for a trial and decide to participate, you should be willing to follow the guidelines of the study.

How can I find out about participating in a hepatitis C clinical trial?

Many trials are being conducted at VA medical centers across the country. There are trials in all Phases, studying many different drugs. Ask your VA doctor about what trials may be appropriate for you.

The decision to participate in a clinical trial is an important personal choice. It is a good idea to know as much as possible about the trial before beginning. You may want to have a list of questions

for the health care providers and study coordinators when you meet with them. You may also want to talk with your regular doctor, friends, and family to help you make your decision.

Where can I get more information on clinical trials?

Write the National Institutes of Health (NIH) at Bethesda, MD 20892
800-411-1222 and visit the Web site at www.clinicaltrials.gov

Write the Food and Drug Administration (FDA)
Office of Special Health Issues at
Parklawn Building, HF-12
5600 Fishers Lane
Rockville, MD 20857
and visit the Web site at www.fda.gov

Who can I contact for more information?

Call your local VA medical center and visit the Veterans Affairs Hepatitis C Web site at <http://www.hepatitis.va.gov/>

Contact the Centers for Disease Control and Prevention (CDC) Hepatitis Toll-Free Information Line at 1-888-4-HEPCDC (1-888-443-7232) and visit the Web site at <http://www.cdc.gov/ncidod/diseases/hepatitis>

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