Hepatitis C Treatment

Hepatitis C Clinical Trials

Pretty much everything we know about viral hepatitis treatment depends on research—and not just any research, but clinical trials involving people with hepatitis C. People living with hepatitis C today have yesterday's clinical trial volunteers to thank for the medications currently available. Similarly, our ability to manage hepatitis C in the future—whether through effective vaccines or novel therapeutic and curative drugs for those people just starting therapy or in desperate need of new agents—will depend greatly on people to continue enrolling in clinical trials.

Of course, deciding to participate in a clinical trial isn't only about altruism—putting the needs of others before our own. Though most people living with viral hepatitis today have treatment options to choose from and do not need clinical trials to access lifesaving therapy, this is not true for everyone. With hepatitis C, some people are at the end of their treatment rope, because they have not been cured using available drugs. There are also individuals who were cured of hepatitis C but are looking for new treatments to help manage the devastating effects of cirrhosis.

Should you join a clinical trial? Like all treatment decisions, this question can be answered only through discussions with your health care provider and others you trust. To help you better understand clinical trials and to have these discussions, we offer the following additional information on the subject.

What Is a Clinical Trial (or Study)?

A clinical trial is a medical experiment that takes place in a hospital, clinic or doctor's office. The experiment may test the safety and usefulness of a new drug, or it may test several different kinds of drugs or treatment strategies to see which one is better. Some clinical trials test drugs that treat viral hepatitis directly, while other trials test drugs that treat or prevent the complications from liver disease or actual liver damage. Studies may also test easier or more effective ways to take medications, or strategies to treat side effects of medications.

The first trials of a new drug performed in humans are known as Phase I studies; they test the safety of the treatment. These studies may also look for early signs of effectiveness, such as viral load reductions after the drug is taken for one or two weeks.

Once Phase I studies are completed, the drug moves into Phase II testing. These studies collect safety and dosing information and begin to see how effective the treatment is when taken for several months.

Phase III studies are larger, longer trials designed to confirm the proper dose, whether or not a treatment works and whether there are important safety issues.

The U.S. Food and Drug Administration (FDA) will review data from all of the trials, along with test tube and animal studies, to determine whether or not to approve the drug. Sometimes, an important new drug is granted “accelerated approval” by the FDA while the Phase III studies are still ongoing. Other times, the FDA requires all studies to be completed before an application for approval can be filed.

Finally, Phase IV studies may evaluate the approved drug in more people and different populations. Phase IV studies, also known as post-marketing studies, are also conducted to test several different approved treatments to find out whether one works better than others.

Some people living with viral hepatitis enter clinical trials to gain access to a doctor or clinic because they may not have any other options for receiving care. Some trials provide the equivalent of free care and medication, but others require that certain tests be covered and that approved meds be provided by the participant. Although enrolling in a study may be a useful part of your treatment, it is important to know that the main purpose of the trial is to test the treatment—not to provide the best possible medical care. Therefore, study participation is not a good substitute for regular doctor visits.

Most, though not all, clinical trials compare at least two different drugs or drug regimens. Many of these studies may have one arm, or group, of people taking a drug regimen that contains at least one experimental drug. They will likely be compared with a “control group”—people living with viral hepatitis receiving the approved standard of care.

Another type of control found in clinical trials uses what is known as a placebo—a fake, sugar or dummy pill—that contains no medicine but looks exactly like the tested treatment. Today, clinical trials for viral hepatitis rarely use control arms in which only a placebo is given. This is because we already have effective treatments, so an experimental drug or regimen needs to show that, when compared with regimens already available, it works at least as well, causes fewer side effects, may not need to be taken for as long or is easier to take.

When studies compare different medicines, a computer may be used to randomly assign you to one of the treatment arms. This is known as randomization. This is important, as it prevents the researchers conducting the study from being biased—for example, assigning patients they already have a relationship with to receive the experimental treatment and those they don’t know to receive a placebo.

Additionally, you may not be told which treatment you are receiving. This is known as a blinded study: Participants don’t know whether they are in the control arm or in the arm receiving the experimental treatment. When neither the study participants nore the doctors know who is in the control group, the study is called double-blind, again to prevent clinical trial staff members from being biased.

The information provided here is specific to the United States. However, most developed countries offer similar regulations for clinical trials.

Why Might I Participate in a Clinical Trial?

People take part in clinical trials for several reasons. Some people do so in order to get a new and otherwise unavailable treatment. Some people participate in order to get free laboratory tests. Also, one of the most common reasons is that participation helps scientists find better treatments for viral hepatitis.

Conversely, there may be reasons not to participate in a clinical trial. For instance, the treatments in the trial may have side effects or be unsafe. Other treatments you may want to take in the future may not work as well because of drugs you took in a clinical trial. Studies may also require hospital stays or invasive tests or procedures. Or you may just not have the time and energy that a study might require.

Is Participating in a Clinical Trial Safe?

One purpose of a clinical trial is to measure the side effects, also called adverse events, associated with using a drug or combination of drugs. If the drug is very new, there may be unknown side effects—potentially serious or even fatal ones. If you experience side effects, you may be taken off the drug or given a lower dose.

Also, new treatments may not work very well. This is important for people with viral hepatitis, because a weaker or less potent drug or regimen may cause your virus to develop resistance to a certain med or whole family of meds. Some trials have “stopping rules” to lower the risk of resistance, so you may have to stop taking an experimental drug because it is not working for you.

As a general rule, the more people who have taken the treatment being studied and the further along in development it is, the more likely that researchers will understand and be able to explain the potential risks of the study.

Some studies today involve experiments that may not offer a personal benefit, but they are critical to research exploring curative treatment approaches. If you decide to enroll in these trials, make sure you understand fully what you are getting into.

Before you enroll in any clinical trial, all the known risks, benefits, rights and responsibilities should be explained to you. This is known as informed consent. During the informed consent process, you should receive a detailed written explanation of the rules of the clinical trial. It should be written in plain, everyday language and should be translated for people who do not understand English. It is important to be sure that you understand everything in the informed consent document and that you keep a copy for yourself. When you are ready, you will be asked to sign the document. You will receive a copy that has been signed by you and the person in charge of the study—the principal investigator—at the clinical trial site. If you don’t understand something, ask questions. Don’t feel

like you are asking too many questions or taking up too much time. Clinical trials need participants like you, and you have a right to fully understand the commitment you are making. It might be helpful to write down the answers to your questions, so that you have the information later on.

However, it is important to know that some questions can't be answered—after all, clinical trials are conducted to answer important questions. For instance, the side effects of a new treatment may not be known. In that case, the person explaining the trial to you may tell you what might happen, but may add that the researchers do not know for sure. Less is known about a drug being studied in Phase I or II.

Each trial has a set of rules. These rules are called the protocol—the blueprint of the study. The protocol includes rules about how often you will need to visit the study site, along with the tests that will be done and whether and when you will be given your test results. These rules should also be explained in the consent form. Again, it is important that you understand the protocol and that you are able to follow it.

If there are any changes to the protocol, a new informed consent may be given to you to read and sign. Again, make sure you understand any changes that are being made along the way before you sign.

Know that the informed consent is not a binding contract—you have the right to withdraw from the study at any time and for any reason.

Who Is in Charge of the Clinical Trial?

The person you will probably deal with most often is the study nurse or study coordinator. He or she will probably explain the informed consent to you, deal with medical tests and blood draws and handle any minor problems that may come up during the trial, such as helping you find transportation to the study site.

In addition, every study site will have a principal investigator (PI). The PI may give you medical examinations during the study, and he or she will be responsible for dealing with any serious medical problems that come up as a result of your study participation. The PI may not know which arm of the study you are in.

Every study site also has an Institutional Review Board (IRB). The IRB is responsible for protecting the rights of participants in a trial. It must approve every trial that is conducted at that institution, and it must review the trial every few months. The IRB can stop a trial if the trial doesn't do what it promised or if it exposes people to harm. You can complain to the IRB if you have a problem while in a study.

Finally, there is the study's Data and Safety Monitoring Board (DSMB), made up of experts who review the information (data) from the trial at different time points and who can delay or stop the study if there are safety concerns.

When you sign the informed consent, you should be given contact information for the study coordinator or study nurse, the principal investigator and the chairman of the IRB. That way, if any problems come up during the study, you can easily contact the right person.

Despite the unknown risks of being in a clinical trial, there are many safety checks and built-in mechanisms to protect you as a study participant.

What Happens When I Try to Enter a Trial?

First, you will be screened by the clinical trial team. This will likely involve some medical tests and lots of questions regarding your health and medical history to determine whether or not you meet the inclusion or exclusion criteria. These are rules about who can and who can't enroll in a particular trial. For instance, a study may exclude people who are taking a specific medication or who have more advanced liver damage or people who have already used certain treatments.

If you qualify for the study, you will be given the informed consent to read and sign. Again, make sure you understand what is in the informed consent. Don't feel pressured to sign it on the spot.

After you sign the informed consent, you are officially enrolled in the study. Usually you'll be asked to have baseline blood draws—for example, lab tests to measure your liver enzyme levels and hepatitis C viral loads immediately before starting an experimental treatment—along with other assessments. This is required so investigators can compare this information with tests performed later in the trial.

What happens after that may vary widely depending on the type of study. For instance, you may be randomized to one of the treatment arms in the study and may not find out which group you're in until after the trial has been completed. You may be randomized but told which study arm you are in. Some studies will put everyone on the treatment being tested, which is known as an open-label trial.

You may be asked to come back often—maybe every week or two at first, followed by visits every few months—for more tests and more blood draws for as long as the study is ongoing. By taking blood draws at intervals during the trial, comparisons can be made to your baseline tests to determine safety and effectiveness.

You will probably be asked about side effects you may have experienced, and you may be asked to report how adherent you were in taking the medication. Some clinical trial researchers may ask you to bring your medication bottles to the site every time you visit so they can count the number of pills left.

You may be given a quality-of-life document to fill out as well. This form looks at how the medications you're using in the study affect things like your moods, activity levels and sleep patterns.

It is important that you continue to see your regular doctor after you enroll in the clinical trial. Ask the people running your study to communicate regularly with your doctor. Make sure that both you and your doctor get copies of any blood tests that are available. Tell your doctor about any side effects that you experience. If you get sick during the trial, make sure to tell your study nurse or principal investigator.

Remember, it's also important to have the phone number of a doctor or nurse involved with the trial whom you can call 24 hours a day, in case you have a problem in the middle of the night. Because the drugs in your trial may be experimental, a doctor in an emergency room may not know what to do if the drug makes you sick.

What Happens When the Trial Is Over?

In some trials, people will get their results before the trial ends—for example, if the treatment is not working, they may stop early. With hepatitis C, you can expect to get your results 12 to 24 weeks after finishing treatment. Usually, if the study was randomized and blinded, you will now be told what treatment you were taking. If the study is ending and if study results are available, you should be given those results.

How Do I Find Out About Clinical Trials?

Your doctor may suggest participating in a clinical trial. You may also be interested in a particular drug in development—Hep often publishes information about various medications in development, notably through our newsfeed.

Other organizations and websites can help you find out about clinical trials. For instance, ClinicalTrials.gov is a site run by the National Institutes of Health that has information about all clinical studies related to viral hepatitis in the United States.

If you are receiving care for hepatitis C at a major hospital, several of the health care providers there may be conducting clinical trials that may be of interest to you. Ask your hepatitis care providers for more information.

In the end, clinical trials have helped provide all the treatments we now have available to us. They have also helped us determine which drugs are the most effective, the safest to use and easiest to take. Whether or not you decide to enroll in a clinical trial should depend on many factors.

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