

Clinical Trials in Liver Cancer

Webinar by the Hepatitis B Foundation and Blue Faery
Presented May 27, 2015 by Jill McNair and Katelyn Levy, BS
Question and Answer Session

When should I think about participating in a clinical trial- as soon as I have been diagnosed with liver cancer or after I have been treated with standard care?

It's a good idea to start thinking of participating in a clinical trial as soon as you have been diagnosed with liver cancer, even before you have started treatment. Trials are available for both people who have not been treated for their liver cancer, as well as for people who have already been treated. Some people would first like to start treatment with the standard of care, while others would like their first line of defense to be participation in a clinical trial.

What if I have already started treatment with another drug- can I still participate in a clinical trial?

Yes, you can participate if you find a clinical trial that allows participation even if you have already been treated with another drug or therapy. However, it's rare for people to participate in a clinical trial for one experimental therapy and then participate in another clinical trial for a different therapy, since it would be difficult to determine what the effects of each therapy are.

Where can I find out about the inclusion/exclusion criteria (whether I am eligible to participate)?

The key criteria are listed on www.clinicaltrials.gov (a service of the U.S. National Institutes of Health) and will be included in the informed consent form. You should also talk to your health care team about the criteria to find out if the clinical trial is right for you, especially if some criteria are very specific.

What about taking supplements or herbal remedies while participating in a clinical trial?

It's very important that you tell your health care team about all supplements or herbal remedies and all other medicines you are taking.

How often are patients in clinical trials prescribed therapies that are off-label (that is, therapies that are being used for conditions for which they have not been approved)?

You should ask if the therapy that is being studied has been approved by the Food and Drug Administration (FDA) to be used for another condition/disease. You will want to know what the side effects of that drug were in the population that it has already been approved for, and whether the side effects are anticipated to be different in your condition.

What kind of treatment will I get if I am randomized to the placebo group in a clinical trial?

Not all clinical trials will have a placebo ("sugar pill") group. If you are going to participate in a clinical trial that has a placebo group, you will be informed about this during the informed consent process. All participants in a clinical trial, regardless of whether they are randomized to a treatment arm or a placebo arm, will get the standard of care— that is, the treatment that you would normally get if you were not participating in a clinical trial. In addition to that, you might get the experimental treatment or the placebo.

What if my doctor is not conducting any clinical trials? How can I find out about trials at other centers?

If your doctor is not conducting any clinical trials, you will have to consider whether you would like to go to another doctor so that you can participate in a clinical trial. That doesn't mean that you can't continue to see your regular doctor; it just means you will also have to see the doctor who is conducting the clinical

trial. To find out what trials are being conducted at different centers, you can search on www.clinicaltrials.gov.

What about the costs of clinical trial participation? Who pays?

This may vary by trial, but generally, if your insurance covers standard of care (that is, whatever care you would receive if you were not in a clinical trial), your insurance company will pay for the standard of care during your clinical trial. Anything that is in addition to standard of care that you will be receiving because you are participating in a clinical trial— such as cost of the experimental therapy or additional testing— will be covered by the clinical study.

Will I get any reimbursement for participating in a clinical trial?

In some trials, participants will receive reimbursements to participate in the trial. These reimbursements may cover the cost of parking or transportation. It's important to remember that if you are going to receive such reimbursements, you will need to fill out additional paperwork and you may need to complete a W9 form and other tax documents. Find out if you will be taxed on the reimbursements.

Who is the main source of information about clinical trial participation before, during and after a trial?

The main contact person for clinical trial participants is the clinical research coordinator. The research coordinator is responsible for the day-to-day activities, scheduling appointments, providing information about reimbursements, and answering questions about the trial. If you have questions about a medical issue, you should also talk to the principal investigator (usually the doctor).

What should I ask my health care team while I am going through the informed consent process?

Be sure to find out as much as possible about what participation will involve. For example, you may want to ask the following:

- What procedures are involved in the study?
- Of those procedures, which are considered to be standard of care (what would I be receiving even if I were not going to participate in a clinical trial)?
- What additional procedures/therapies am I getting or not getting because I am participating in a clinical trial?
- What are the known risks and what are the anticipated risks?
- What are the costs? Who will pay for the standard of care and who will pay for the procedures/therapies that are available only to those people participating in a clinical trial?

Where to get more information about participating in clinical trials

- www.clinicaltrials.gov (comprehensive clinical trials data base by the National Institutes of Health)
- www.Cancer.gov (National Cancer Institute): Call NCI's Cancer Information Service (CIS) at 1-800-4-CANCER (1-800-422-6237). The CIS provides free help in English and Spanish from 8:00 a.m. to 8:00 p.m. Eastern time in the United States. All calls are strictly confidential.
- CISC RP has several services to help patients and families find clinical trials
 - o Complete a form on www.Searchclinicaltrials.org or call **1-877-MED HERO** to have CISC RP perform a custom search for you
 - o Perform your own [search of the CenterWatch Clinical Trials database](#)
 - o Get information about clinical trial participation at the CISC RP education center on www.ciscrp.org
- www.livercancerconnect.org, a dedicated program of the Hepatitis B Foundation, has a directory of [liver cancer centers](#), a [Drug Watch](#) and a clinical trials directory.