LYMPHOMA
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Getting the Facts

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Understanding Clinical Trials

Clinical Trials Overview

A clinical trial (also called an interventional study or clinical study) is a research study conducted to answer specific questions about new ways to prevent, diagnose, treat, or manage a disease or the side effects caused by a new or existing treatment. Participation in a clinical trial contributes to medical knowledge. The investigators in clinical trials want to determine the safety and effectiveness of the treatment being investigated by making specific assessments before, during, and after the trial.

Some common reasons for conducting clinical trials include:

- Evaluating one or more products/interventions (i.e., drugs, medical devices, approaches to surgery or radiation therapy) for treating a condition, disease, or syndrome
- Finding ways to prevent the initial development or recurrence of a disease or condition, including medicines, vaccines, or lifestyle changes, such as diet, among other approaches
- Evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition, or identifying a condition or risk factor for that condition
- Exploring and measuring ways to improve the comfort and quality of life of people with a chronic illness through supportive care

Most new treatments go through at least three trial phases (Phases I, II, and III), which are defined by the U.S. Food and Drug Administration (FDA), before becoming a standard therapy that is used in hospitals and clinics. Each phase is designed to find out certain information, building upon the information learned from the previous phase. Patients may be able to take part in different stages depending on their health status, their type and stage of cancer, and the type of treatment, if any, that they have already received. Patients participating in clinical trials are watched carefully during treatment.

Phase I

Phase I studies investigate the best way to give a treatment and how much of it can be given safely. The treatment under investigation will have already been tested in a laboratory and on animals, but scientists need to see how it works in people. This phase has the most risks; it is usually only offered to a small number of people (10 to 15) who have not been helped by standard treatment.

Phase II

Once a therapy is shown to be safe in Phase I, it is tested in Phase II. This phase continues to monitor safety, but also looks at the effect of the treatment on the cancer and the patient.

Phase III

When the treatment gets to Phase III, it has been shown to be safe and effective. This phase tests the treatment on a large number of patients to confirm the results found in the first two phases. This phase also compares the new treatment with the standard treatment.

Participating in a Clinical Trial

Clinical trials may offer many benefits and risks. People in clinical trials may be able to try new treatments that are not available to all patients and are monitored very closely. However, being part of the trial might mean that you receive the standard therapy. If you receive the new treatment, it may or may not be more effective than the standard one. The healthcare team studying the new treatment will explain all of the possible risks and benefits of a specific clinical trial to you.

Every clinical trial is led by a principal investigator, who is often a medical doctor. Clinical trials also have a research team that may include doctors, nurses, social workers, and other healthcare professionals. Patients usually continue regular visits with their current healthcare provider who may work with the research team to ensure that any investigational treatment would not interfere with current medication or treatments.

Informed Consent

Informed consent is the process in which you learn about all of the expected risks, potential benefits, and alternatives of a clinical trial. After the healthcare team explains everything and you do not have any more questions, you will be asked to sign an informed consent form. Each person participating in a clinical trial must sign an informed consent document before entering a study to show that he or she was given information on risks, potential benefits, and alternatives and understands it. Remember, you can leave a clinical trial at any time. If you leave, or if you decide not to take part, your doctor will discuss the other treatment options available to you.

Questions to Ask About Clinical Trials

Here are some sample questions you may want to ask in addition to knowing about the potential benefits and risks:

- What is the purpose of this clinical trial?
- Why are you recommending this clinical trial for me?
- Who is sponsoring this trial (the National Cancer Institute [NCI], a cancer center, a pharmaceutical/biotechnology company)?
- Who has reviewed and approved this clinical trial?
- Does this clinical trial include the use of a placebo (no active ingredient/no intervention)?
- How long will the study last? Where will it take place?
- Do I always have to travel to the trial location in order to be monitored/receive follow-up care?
- What are the risks involved?

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- What are the possible benefits? If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- What are my responsibilities during the clinical trial (e.g., take oral medications/appear for treatments, report side effects, attend follow-up visits/tests, complete questionnaires, etc.)?
- What kind of tests, procedures, or treatments will be performed? How many and how often?
- Will I be in any discomfort or pain?
- What costs will I be responsible for? Who will pay for my participation? Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this trial?
- What happens if my health gets worse during the clinical trial? Who do I contact?

Use of Placebos in Phase III Studies

A placebo, or sugar pill, is an inactive ingredient that is used as a comparator in some clinical trials. Cancer trials testing a drug or therapy regimen rarely place patients into a placebo group in which they do not receive active treatment for their disease. In Phase III trials, patients are usually selected at random for either the experimental group receiving the study drug or the control group receiving the current standard treatment for their particular lymphoma. Many patients who are in the control group still benefit from the standard of care.

Cost Associated With Participating in a Clinical Trial

Clinical trials (studies) are very expensive undertakings for the study sponsor. However, the cost to the patient varies depending on the study, who is sponsoring the study, what portion of the study-related expenses the sponsor will cover, and the patient's health insurance coverage. According to the Affordable Care Act, health insurance plans issued after January 1, 2014, cannot limit or deny coverage for people who want to participate in approved clinical trials. Plans existing before this date may or may not provide coverage for the basic medical procedures associated with the trial, such as lab tests, scans, and hospitalization when required. Medicare provides coverage for patient care associated with most clinical trials. If a patient is taking part in an NCI trial being conducted at their campus located in Bethesda, Maryland, the NCI will pay for the study drug and the costs related to the study. Additional funding to assist with travel, food, and lodging expenses is also provided. Some cancer centers provide financial assistance or discounted rates for room and meals and have special research units that will pay for study-related costs. There are also organizations that will provide financial assistance for treatment-related expenses. (For more information, please refer to the Lymphoma Research Foundation's [LRF's] *Resources for Financial Assistance* fact sheet.)

Finding Out About Lymphoma Clinical Trials

There are many ways to find out about clinical trials: Your doctor may be able to tell you about some clinical trials. Call the LRF Helpline at (800) 500-9976 or helpline@lymphoma.org and request a clinical trial search. Comprehensive cancer centers in your area may also have information about clinical trials for your type of lymphoma. Call the NCI's Cancer Information Center at (888) NCI-1937 or the NCI's Clinical Trials Referral Office at 800-4-CANCER. Search the NCI's websites (www.cancer.gov or www.clinicaltrials.gov) for user-friendly, comprehensive clinical trial listings and matching services for patients and professionals. In addition, the Coalition of Cancer Cooperative Groups website (www.cancertrialshelp.org) is also a helpful resource.

Resources

LRF offers a wide range of resources that address treatment options, the latest research advances, and ways to cope with all aspects of lymphoma, including our award-winning mobile app. LRF also provides many educational activities, from in-person meetings to teleconferences and webcasts, as well as disease-specific websites, videos, and eNewsletters for current lymphoma information and treatment options. To learn more about any of these resources, visit our website at www.lymphoma.org, or contact the LRF Helpline at (800) 500-9976 or helpline@lymphoma.org.