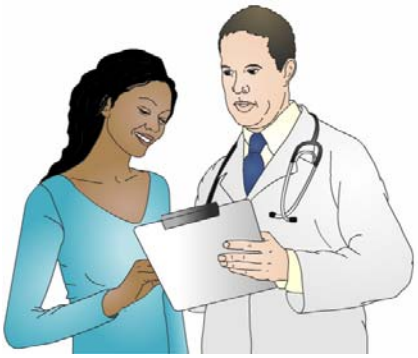
Clinical Trials

Introduction



A clinical trial is a study done to evaluate new treatments. You may be interested in or asked to enter a trial. The decision whether or not to enter a clinical trial is yours. This reference summary will help explain clinical trials and help answer some of the most common questions.

What Is a Clinical Trial?

A clinical trial is a study conducted to evaluate new treatments. Each study is designed to find better ways to help patients.

Before a new treatment is tried with patients, it is carefully studied in the laboratory. This research points out the new methods most likely to succeed, and helps to show how to use them safely and effectively.

The most promising results of that research are tried in patient studies. These will hopefully lead to findings that may help future patients. This early lab research, however, cannot predict the exact ways a new treatment will work with patients. With any new treatment risks as well as possible benefits exist. There may also be some risks that are not yet known.

Clinical trials help us find out if a promising new treatment is safe and effective for patients. During a trial, more and more information is gained about a new treatment, its risks, and how well it may or may not work.

Why Are Clinical Trials Important?

Clinical trials are needed in cases where existing treatments do not offer patients satisfactory results. New treatments must prove to be safe and effective with a certain

Last reviewed: 06/08/2016

number of patients before they can be made widely available.Through clinical trials, researchers learn which approaches are more effective and safer than others. This is the best way to test a new treatment.

Treatments being used now are known as standard treatments. Standard treatments were first shown to be effective in clinical trials. Researchers always use clinical trials to help find new and better treatments.

Why Should You Be Interested in a Clinical Trial?

Patients take part in clinical trials for many reasons. They foremost hope that this new treatment will help them survive longer and possibly be cured. The new treatment may allow an improved lifestyle. Often they want to contribute to a research effort that may help others. This may include children and parents, especially in cases of diseases that run in families.

Many trials have turned out to be better than standard treatments; others have either been not as good as or no better than the treatments already being used. Although there is always a chance that a new treatment will be disappointing, the researchers involved in a lab study have reason to believe that it will be as good as, or better than, current treatments. The patients who take part in clinical trials that do prove to be better treatments have the first chance to benefit from them.

How a treatment will work for a patient in a trial cannot be known ahead of time. Patients should choose if they want to take part in a study or not only after they understand both the possible risks and benefits.

Informed Consent

Informed consent means that, as a patient, you are given information so you can understand what is involved in a trial, including its potential benefits and risks, and then decide freely to take part in it or not. Informed consent is required in studies that are regulated or funded federally, as well as by many state laws.

First, the doctors and nurses involved in the trial explain the nature of the treatment.

Last reviewed: 06/08/2016

This reference summary is part of the explanation procedures. Then you are given an informed consent form to read and consider carefully. If you agree to take part, you can sign the form. Of course, you may also refuse.

If you enter a trial, you will continue to receive any new information about your treatment that may affect your willingness to stay in the trial. Signing a consent form does not bind you to the study. You can still leave at any time.

If you have any questions at any time about any part of the study, be sure to ask your doctors. If you are not satisfied with the answers, you may consider leaving the study. If you decide to leave, it will not be held against you. Don't be afraid that you will receive no further care. You can freely discuss other possible treatments and care with your doctors and nurses.

How Are Clinical Trials Conducted?

The doctors who conduct a clinical trial follow a carefully designed treatment plan called a "protocol." This spells out what will be done and why. Studies are planned to safeguard the medical and psychological health of the patients as well as to answer research questions.

Patients may be eligible for clinical trials, depending on their general condition and specific disease. Clinical trials are carried out in phases, each designed to find out certain information.

Some clinical trials test one new treatment in one group of patients. Other trials compare two or more groups of patients. Researchers make sure that the patients in different groups are similar in certain ways, such as the nature and stage of their disease.

One of the groups may receive standard treatment and the other group the new treatment. The group receiving the standard treatment is called the "control" group.

Sometimes, no standard treatment yet exists. In drug studies for such cases, one group of patients might receive a new drug and the control group, none. But no patient is placed in a control group without treatment if there is any known treatment that

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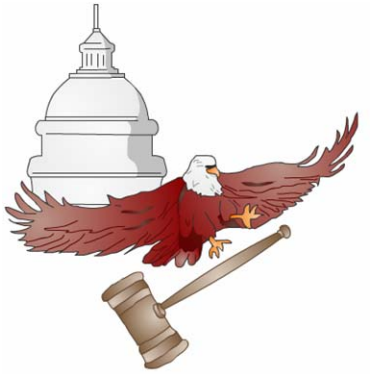
would benefit that patient. The control group is followed as often and carefully as the treatment group.

One of the ways to prevent the bias of a patient or doctor from influencing the study results is “randomization.” If a patient agrees to be randomized, this means he or she is selected by chance, like tossing a coin, to be in one group or another. The researchers do not know which treatment is best. From what is known at the time, any one of the treatments chosen could be of equal benefit to the patient.

If the treatment in a trial is not helping the patient, the patient’s doctor can decide to take him or her out of the study. If a treatment is found to be too harmful or not effective, it is stopped. Also, when there is firm evidence that one method is better than others in a study, the trial is stopped and the participants in the trial may be offered the benefit of the new treatment.

What Protection Do You Have as a Patient in a Clinical Trial?

The ethical and legal codes that govern medical practice apply to clinical trials. In addition, most clinical research is federally regulated with built-in safeguards to protect patients.



Any well-run clinical trial, whether federally supported or not, is carefully reviewed for medical ethics, patient safety, and scientific merit by the research institution. Every study should provide for monitoring the data and the safety of patients on an ongoing basis.

After patients join a clinical trial and it progresses, doctors report the results of the trial to scientific meetings, to medical journals whose articles are approved by experts, and to various government agencies. Your name will remain anonymous and will not be mentioned in these studies.

Are You Eligible for a Clinical Trial?

Every clinical trial is designed to answer a set of research questions. If you fit the guidelines for a trial, you may be eligible to take part. Your doctor may determine that you fit the guidelines for a clinical trial.

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Summary

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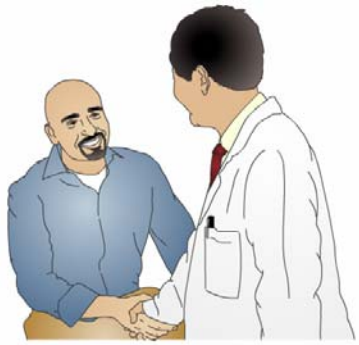

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