

WHAT IS A CLINICAL TRIAL?

What is the purpose of clinical trials?

Clinical trials are research studies designed to see if new medical treatments work like they are supposed to. Each trial is focused on one specific question about health care. Some clinical trials test new medicines or a new use of an old medicine. Others test medical devices or surgical procedures.

Who can enroll in clinical trials?

Each clinical trial specifies criteria for the type of people and illness that particular trial is means to study. “Inclusion criteria” describe the conditions that you must have to be in the trial. “Exclusion criteria” describe the conditions that would exclude you from participating in the trial.

How can I learn more about a specific clinical trial?

Ask your doctor if it is appropriate for you to participate in a clinical trial. They may refer you to the Epilepsy Clinical Trials Program.

What is the difference between drugs in a clinical trial and drugs that are not?

Medicines available by prescription have been through rigorous testing for both safety and effectiveness and have been approved by the FDA (Food and Drug Administration). This process nearly always includes clinical trials. Drugs used in clinical trials have been through many levels of safety testing, but some studies have yet to be done to complete their evaluation.

How could being in a clinical trial benefit me?

Participating in a clinical trial may benefit you but the most important benefit is to society because the information learned in a clinical trial is used to help other people with epilepsy. However, you may benefit because:

- (1) Participation in a clinical trial includes access to medical experts.
- (2) Some trials include a variety of free medical tests that may improve your health in other ways.
- (3) Clinical trials provide study drug and medical care free to the patient and may pay for your time.
- (4) Being in a clinical trial usually allows access to new treatments that aren't yet available to the general public.

What is the time commitment of being in a clinical trial?

The time commitment is different for each clinical trial. Most epilepsy clinical trials are completely outpatient, though some require admission to the hospital for a few nights. Clinic visit typically take 1 ½-2 hours and include the things you would normally do during a clinic visit, such as talking to you about your seizures and examining you, but they also usually involve drawing blood, obtaining and ECG heart rhythm tracing, and a urine specimen. Clinic visits occur every few weeks or months and may go on for at least months, and sometimes years.

Can I quit a clinical trial if I don't like it?

You always have the option to leave a clinical trial. However, it is important to stop epilepsy medications slowly, rather than all of a sudden, so it is important to discuss any concerns you have with the study doctor before stopping any medication. Although you can always leave a clinical trial, it is important to know that when you enroll in a clinical trial you are committing to completing the trials unless a significant problem arises.

Are clinical trials safe?

Treatments in clinical trials have been tested for safety in some settings before the trial begins. Epilepsy drugs are usually tested first on animals and then in normal volunteers who do not have epilepsy. Early in development of a medication, there may be little known about the medication, since few people have taken the drug. Most clinical trials are performed later in development when many people have taken the drug and more is known about its safety. Clinical trials are designed so the doctors and nurses are aware of any side effects that develop. Participants are monitored frequently and the information is reported to the government and to other doctors whose main job is to oversee the safety of the trial. If enough concerns are raised about the safety of the treatment, the study is stopped.

What is a placebo?

A placebo is a pill that contains no medicine. It is often called a “sugar pill”. Placebos are used in some clinical trials, but many trials do not use placebos. By giving a study medicine to half a group of patients and a placebo to the other half, the two groups can be compared to see if the study medicine worked better than the placebo. If a patient has a medical condition for which there is a known treatment that would or might help them, they are never given placebos. In that case they would always get a treatment so that people do not have their illness untreated.

What is meant by “blinding”?

Blinding is an important part of many clinical trials and has nothing to do with your vision. Blinding is the process of making sure that neither the doctors nor the patients know which study treatment a specific patient is receiving (for example, study medicine or placebo). Blinding ensures that patients’ and doctors’ personal opinions about the treatment do not affect the results of the study.

Will I hear the results of the Clinical Trial?

You will typically not be told the results of a trial, because the results will not be available for a long time. You certainly have the right to know the results of a trial and the final results are not kept secret so you can ask the study team for the final results. However, it often takes many years for the results of a clinical trial to be fully evaluated and reported. These results focus on the treatment studied and do not mention any details about specific participants.

Should I be in a clinical trial?

The decision to be in a clinical trial is an individual process that depends upon the specific person and the illness they face. Doctors and nurses involved in specific clinical trials will be happy to discuss the details of the trial with you so you can make an informed decision that is best for you. Nobody is ever forced to be in a clinical trial.

Where can I learn more information?

A list of ongoing clinical trials can be found at: www.clinicaltrials.gov

A related website that provides information about participating in clinical trials is at: <http://clinicaltrials.gov/ct2/info/understand>

Gabriel Martz, MD 10/29/09