EmergingMed® - About Clinical Trials

What is a clinical trial?
A clinical trial is a scientific study of how a new medicine or treatment works in people. Through clinical trials, doctors find new and better ways to prevent, detect, diagnose, control, and treat illnesses. People who participate in clinical trials are not guinea pigs.

How is the safety of the participant protected?
The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built-in safeguards to protect the participants. The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants’ names are kept confidential and are never mentioned in reports.

What is informed consent?
Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. If the participant’s native language is not English, translation assistance can be provided. The research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are also explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

What are the phases of clinical trials?

Phase I trials: A phase I trial evaluates how a new drug should be taken into the body (by mouth, injected into the blood, injected into the muscle, etc.) how often, and what dose is safe. In particular, these studies are looking for the highest dose that can safely be given with the fewest serious side effects (maximum tolerated dose). In addition, a Phase I trial might evaluate a new combination of 2 drugs. In these trials one or both of the drugs, might be well known but doctors have never before studied the two together. In these combination studies, doctors watch closely for potential interactions and new side effects when the two drugs are given together. Patients in a phase I trial will receive the investigational treatment.

Phase II trials: A phase II trial continues to test the safety of the drug, and begins to evaluate how well the new drug works. Phase II studies usually focus on a particular aspect of a disease. In most phase II trials, they do not test the difference between two therapies, so the participants will almost always get the experimental treatment.

Phase III trials: A phase III trial tests a new drug, a new combination of drugs, or a new surgical procedure in comparison to the current standard for treatment. A participant will usually be assigned to the standard treatment group or the new treatment group at random (called randomization). In phase III trials, patients rarely receive a placebo. Placebos are typically only given when there is no standard therapy for the disease. People who participate in phase III clinical trials will either receive the best available standard therapy or the experimental therapy, with an equal chance of receiving either treatment.
What is a placebo?
A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the experimental treatment’s effectiveness. The participants who receive a placebo instead of an active drug or experimental treatment are placed into control group. Participants who are randomly assigned to the control group are monitored the same as patients receiving the experimental treatment.

When is the best time to search for clinical trials?
The best time to search for clinical trials is when you review your treatment options.

Who sponsors clinical trials?
Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies. In addition, federal agencies such as the National Institutes of Health (NIH) sponsor clinical trials. Trials can take place in a variety of locations, such as hospitals, universities, doctors’ offices, or community clinics.

Does a participant continue to work with a primary health care provider while in a trial?
Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but do not provide extended or complete primary health care. In addition, by having the primary health care provider coordinate with the research team, the participant can ensure that other medications or treatments will not conflict with the protocol.

Who is responsible for the costs of care for people taking part in a clinical trial?
The costs of care for people participating in a clinical trial fall into two general categories: 1) routine care costs and 2) research costs. Routine care costs are costs associated with treating a person’s diagnosis whether or not they are in a trial. These costs are usually covered by health insurance, but requirements vary by state and type of health plan. Research costs are costs associated with conducting a clinical trial; these costs may include the costs of extra doctor visits, extra tests, and procedures that are required for the trial but would not be part of routine care. Research costs are usually covered by the organization that sponsors the trial.

Many states require that insurance companies cover the costs of routine care for people taking part in a clinical trial. In other states, voluntary agreements between the states and insurance companies include such a provision. However, coverage varies by state, by health insurance plan, and by type of clinical trial.