FACTS FOR LIFE

Clinical Trials

What is a clinical trial?

Clinical trials are carefully controlled research studies in which people volunteer to participate. These studies test the safety and potential benefits of new ways to diagnose, treat or prevent disease. They also identify risks that may not yet be known. Clinical trials have led to many medical advances, such as screening mammography, lumpectomy and the use of tamoxifen.

There are three main types of clinical trials:

Phase I tests to see if a new treatment is safe for humans and to look for early signs of effectiveness

Phase II tests to see if the treatment works for a specific disease

Phase III compares the effectiveness of the new treatment against a standard treatment

Before a treatment is tested in a clinical trial, it has been studied in a laboratory. Laboratory research helps identify therapies which could benefit breast cancer patients. However, treatments that seem to work well on animals in the lab do not always work as well for people.

That is why clinical trials are needed — to determine the safety and effectiveness of a treatment in humans.

Enrolling in a clinical trial

Following a breast cancer diagnosis, you are faced with many decisions. One of the most important decisions is about treatment. Clinical trials are an excellent way to receive treatment, but are not an option for everyone. With the help of your doctor, you can make an informed choice. On the back of this fact sheet is a list of the pros and cons of joining a clinical trial, as well as a list of resources where you can get more information on clinical trials. Review this information and write down your questions. Then talk to your doctor. Your questions are important, and most doctors will take the time to go over them with you. Also, try to get input from co-survivors (family and friends) who are important in your life. They may also be affected by your treatment decision.

To protect people and to provide consistent testing procedures, clinical trials must follow a strict plan called a *protocol*. The protocol follows medical, ethical and legal guidelines to ensure patient safety. As part of the *protocol*, a person may be randomly assigned to one of two study groups — one group that receives the treatment being studied and one that receives the standard treatment. Many people are concerned about receiving a placebo, or sugar pill, instead of life-saving treatment. Placebos are not used in cancer clinical trials.

Informed consent

Before enrolling in a clinical trial, you must sign an informed consent form. You will be asked to read the form or can have it read to you. This form describes what will be involved in the clinical trial, including possible risks and benefits. Read this form carefully or go over it with your doctor. If there are parts of it you do not understand, ask your doctor or the doctor leading the study to explain it to you. Remember, you can leave the study at any time if you feel it is no longer in your best interest to participate.

Resources

If you would like more information about clinical trials or specific studies currently being conducted, contact one of the resources listed below.

Organizations

American Cancer Society
1-800-ACS-2345
www.cancer.org

National Cancer Institute 1-800-4-CANCER
www.cancer.gov/clinicaltrials

Internet

BreastCancerTrials.org
www.breastcancertrials.org

CenterWatch Clinical Trials Listing Service™
www.centerwatch.com

National Institutes of Health
www.clinicaltrials.gov

The pros and cons of clinical trials

People with breast cancer who are thinking about entering a clinical trial should discuss the risks and benefits with their doctor. For some, it may be best to use standard treatment. Others may be excellent candidates for treatments being tested in clinical trials. Some of the pros and cons of joining clinical trials are listed below.

Pros

- You could have the chance to get a new treatment that may be more effective than the standard therapy.
- You will be helping to add to new research that could improve cancer treatment in the future.
- Even if you are not assigned to receive the new treatment, you will still get the best standard treatment that is available.

Cons

- You may feel that because the treatment being tested is new, it is better than standard treatment. However, for you, the new treatment may not work as well as the standard treatment.
- If the study is a randomized trial, you cannot choose among the treatment options (you will be assigned to one treatment or another).
- The new treatment being tested may have unexpected side effects.
- In some cases, your insurance company may not cover all the costs associated with being in a clinical trial. Usually, extra costs are paid for by the research program, but it is important to ask about this.

Related fact sheets in this series:
- Current Research on Drugs & Treatments
- Making Treatment Decisions
- Treatment Choices — An Overview

The above list of resources is only a suggested resource and is not a complete listing of breast health and breast cancer materials or information. The information contained herein is not meant to be used for self-diagnosis or to replace the services of a medical professional. Komen does not endorse, recommend or make any warranties or representations regarding the accuracy, completeness, timeliness, quality or non-infringement of any of the materials, products or information provided by the organizations referenced herein.

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