FACTS FOR LIFE

Clinical Trials

What is a clinical trial?

Clinical trials are research studies done in people to test the benefits and risks of new ways to detect, diagnose, treat or prevent disease. People volunteer for these studies. Here we discuss breast cancer treatment trials.

Treatment clinical trials have led to many medical advances for breast cancer, such as the use of hormone therapy and chemotherapy.

Before a treatment is tested in a clinical trial, it's studied in a lab. Even though some treatments seem to work well in the lab they don't always work in people. That's why clinical trials are needed — to make sure the treatment is safe and effective for people.

There are 3 main types of clinical trials:

Phase I (phase 1) studies whether a new treatment is safe to use over a range of doses. The treatment may be given to people with different types of cancer.

Phase II (phase 2) studies how well the treatment works for a certain cancer (such as breast cancer).

Phase III (phase 3) studies how well the new treatment works compared to the standard treatment.

Not all clinical trials fall neatly into 1 category. Some trials may be a combination of 2 categories, such as a phase I/II or phase II/III trial.

Enrolling in a treatment clinical trial

After a breast cancer diagnosis, you are faced with choices about treatment. Clinical trials offer the chance to try new treatments and possibly benefit from them. They may not be an option for everyone though. With the help of your doctor, you can decide if a clinical trial is right for you.

To protect people and to provide consistent testing, clinical trials must follow a strict plan called a protocol. The protocol follows medical, ethical and legal guidelines to ensure your safety.

Many people are worried about getting a placebo, or sugar pill. You are never given a placebo in place of an effective treatment. You will either get the new treatment or the standard treatment. Even if you do not get the new drug (or other new therapy), your breast cancer will still be treated as if you weren't in the trial. Most often placebos are not given in a breast cancer treatment trial. Sometimes, you may get the standard treatment plus a placebo rather than the standard treatment plus a new treatment.

Informed consent

Informed consent reviews the risks and benefits of the study and other treatment/trial options. It's required for all clinical trials. Before joining a trial, a research coordinator, doctor or nurse will go over the study protocol with you. He or she will answer any questions you have. Once you decide to join the study, you will be asked for your written permission. The document you sign is called a consent form. You will get a copy.

Remember being in a clinical trial is your choice. You may leave the trial at any time, for any reason. Consenting and giving written permission to join the study doesn't force you to stay in the study.

For more information, visit komen.org or call Susan G. Komen's breast care helpline at 1-877 GO KOMEN (1-877-465-6636) Monday through Friday, 9 AM to 10 PM ET.

The pros and cons of clinical trials

People with breast cancer who are thinking about joining a clinical trial should discuss the risks and benefits with their doctor. Some of the pros and cons of joining are listed below.

Pros

- You have the chance to try a new treatment that may be better than the standard therapy.
- You are helping improve cancer treatment in the future by adding to research.
- Even if you do not get the new treatment, you will still get the best standard treatment available.

Cons

- The new treatment may not work as well as the standard treatment.
- If the study is a randomized trial, you cannot choose which treatment you get (you will be assigned to one treatment or another).
- The new treatment being tested may have unexpected side effects.

Susan G. Komen® Clinical Trial Informational Helpline

Susan G. Komen® is pleased to offer a clinical trial information helpline for those in need of clinical trial information, support and resources. To speak to a Komen Clinical Trial Information specialist, call toll-free 1-877 GO KOMEN (1-877-465-6636) or email at clinicaltrialinfo@komen.org.

Special thanks to Odonate Therapeutics™ for sponsoring the Breast Cancer Clinical Trial Information Helpline.

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Cost

The cost of a new treatment or test being studied is usually paid by the clinical trial. The Affordable Care Act requires insurance companies to cover non-research, standard care costs related to a clinical trial (not covered by the trial itself) plus any standard treatment given. Before enrolling in a clinical trial, talk with your insurance provider and find out exactly which costs are covered (and which are not). This ensures you don't have any unexpected costs, such as going to a lab or provider which may be out-of-network.

Resources

For more information about clinical trials or specific studies currently recruiting participants, contact one of the resources listed below.

BreastCancerTrials.org
In collaboration with Susan G. Komen®,, BreastCancerTrials.org offers a custom matching service to help you find a clinical trial that fits your health needs.

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

National Institutes of Health
www.cc.nih.gov/
www.clinicaltrials.gov/

Coalition of Cancer Cooperative Groups
www.cancertrialshelp.org/

Related fact sheets in this series:
- Breast Cancer Prognosis
- Making Breast Cancer Treatment Decisions