CLINICAL TRIALS

The pros and cons of clinical trials

If you are considering a clinical trial, discuss the risks and benefits with your doctor. Some of the pros and cons are listed below.

Pros

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

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.

What is a clinical trial?

Clinical trials test the safety and benefits of new treatments as well as new combinations (or new doses) of standard treatments. They can also study other parts of care including risk reduction, diagnosis and screening. People volunteer to take part in these research 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 4 main phases of clinical trials:

Phase 1 (phase I)	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 2 (phase II)	Studies how well the treatment works for a certain cancer (such as breast cancer).
Phase 3 (phase III)	Studies how well the new treatment works compared to the standard treatment.
Phase 4 (phase IV)	Studies the long-term side effects of treatments or answer new questions about the 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.

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.

CLINICAL TRIALS

Susan G. Komen® Clinical Trial Information Helpline

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

Resources:

BreastCancerTrials.org
in collaboration with Komen offers a custom matching service to help you find a clinical trial that fits your needs. They also provide a Metastatic Trial Search Tool.

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

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

Related educational resources:

- Breast Cancer Prognosis
- Making Breast Cancer Treatment Decisions

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 are not an option for everyone though. All clinical trials have specific criteria for joining the study, so you may not be eligible for a trial. Or, there may not be a clinical trial currently recruiting participants that's right for you. 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.

Placebos (or sugar pills) aren't used in metastatic breast cancer clinical trials and aren't commonly used in non-metastatic breast cancer trials. You are **never** given a placebo instead of an effective treatment. You will either get the standard treatment or the new treatment. Even if you do not get the new drug (or other new therapy), your breast cancer will be treated the same as if you weren't in a trial. Sometimes in a non-metastatic breast cancer trial, you may get the standard treatment **plus** a placebo rather than the standard treatment **plus** the new treatment.

Informed consent

Informed consent is the process of reviewing the risks and benefits of the study. 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 and answer any questions you have. If 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 voluntary. 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.

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.