

Every year, an estimated one million Americans participate in clinical trials to help researchers gather important information about the benefits and risks of new drugs and treatment methods. In recent surveys, the majority of these participants reported receiving excellent care and viewed their participation as a positive experience. Thanks to patients enrolled in clinical trials, researchers have been able to identify new and effective treatments for various types of cancer. These treatments have the potential to become the new standard of care offered to future patients.

ACRIN Study Participation

Your doctor has asked you to consider joining this study because you have been diagnosed with breast cancer and will have chemotherapy before surgery to treat your disease. The study is coordinated by the American College of Radiology Imaging Network (ACRIN), a member of the National Cancer Institute's Clinical Trials Cooperative Group Program.

Why Is This Study Being Done?

This research study is being done to evaluate the imaging agent [18F] fluorothymidine, often referred to as "FLT". Imaging agents are drugs that are given before or during an imaging scan to more clearly show the difference between tumor tissue and normal tissue. The study doctors want to know if FLT is helpful for predicting the success of chemotherapy in shrinking breast cancer tumor.

Doctors hope to learn if FLT given before a positron emission tomography (PET) scan will produce images that show how the tumor responds to chemotherapy. It is hoped that FLT-PET scans done before and during your chemotherapy will show whether your tumor is growing or shrinking. The study goal is to learn if FLT-PET can help doctors to determine as early as possible if treatment is working.

About FLT-PET – PET is a nuclear medicine imaging scan that creates a 3-D image that provides information about cell function and shows the difference between healthy tissue and diseased tissue. In this study, FLT will be used as a tracer during the PET scan to show how the tumor responds to chemotherapy.

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Funded by the National Cancer Institute

A Study for Patients with Breast Cancer

Evaluating if FLT-PET can determine chemotherapy success



ACRIN[™]
AMERICAN COLLEGE OF
RADIOLOGY
IMAGING NETWORK

Frequently Asked Questions

■ Who can take part in this study?

You may be eligible for this study if you:

- Were diagnosed with breast cancer
- Will have chemotherapy before surgery
- Agree to use birth control while in the study if you are of childbearing age and are sexually active.

You cannot join this study if you:

- Were previously treated for breast cancer with chemotherapy, radiation, surgery, or hormone therapy
- Are under 18 years of age
- Have uncontrolled ongoing illness or other major medical problems
- Have a history of allergic reactions to substances similar to FLT (The study doctor or nurse will discuss with you.)
- Are unable to lie still for 1.5 hours for PET scanning
- Were previously diagnosed with cancer less than five years ago -- (other than skin or cervical)
- Are currently on hormone therapy.

■ How long will I be in the study?

Your participation in this study will last as long as your chemotherapy treatment

■ What if I choose to be in this study?

If you enroll in the study, you will have:

- A screening visit to discuss your study participation
- Three FLT-PET scans at the following times:

1. Before the start of chemotherapy
2. Five to ten days after the start of chemotherapy
3. Five days after the completion of chemotherapy.

In addition, some of the tumor tissue removed during your surgery will be sent to Virginia Commonwealth University for research study. Results from the study done on this tissue will not affect your treatment or prognosis.

■ What if I choose not to participate or, if I join the study can I decide to stop participation?

Study participation is voluntary, and you may choose to stop at any time.

■ What are the side effects of the study?

All participants will be carefully watched for any side effects as a result of the FLT-PET scan. Side effects are usually mild. Your doctor or nurse will discuss any possible side effects in more detail at your screening visit.

■ Are there benefits to taking part in the study?

This is not a treatment study and you are not expected to receive any direct medical benefits from your participation. The information learned from this study may lead to better treatment in the future for patients with breast cancer

■ What are the costs?

ACRIN will pay for the costs of the FLT-PET scans and any diagnostic costs that are part of the study.

You or your insurance will be billed for any treatments or procedures that are a part of the standard of care for your cancer (these are the costs that you would have whether or not you participated in this research study).

■ Is there any payment for participation?

ACRIN does not pay study participants to enroll in a clinical trial. However, reasonable travel expenses, parking and meals associated with participation in this study will be reimbursed. If you complete all four of the research-related visits in this study, you will receive \$180. If you do not complete all the visits, you will be reimbursed \$45 for each visit you did complete.

■ What are my rights if I choose to take part in this study?

Study participation is voluntary, and you may choose to stop at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

"Doctors are learning earlier whether or not treatment is working for a patient because of the progress of cancer research. This allows patients who are getting better to continue with their treatment and patients who are not getting better to try something different. If this trial can predict who will and who will not respond to their chemotherapy as early as possible it will be a big step towards providing the best treatment for each patient. The only way we learn the best way to treat cancer is through clinical trials and I hope as many patients as possible will consider joining this trial."

— Barbara LeStage
ACRIN Patient advocate and breast cancer survivor