To find out more about the

PET SCAN STUDY

Please call 631-632-6245

All calls kept confidential.

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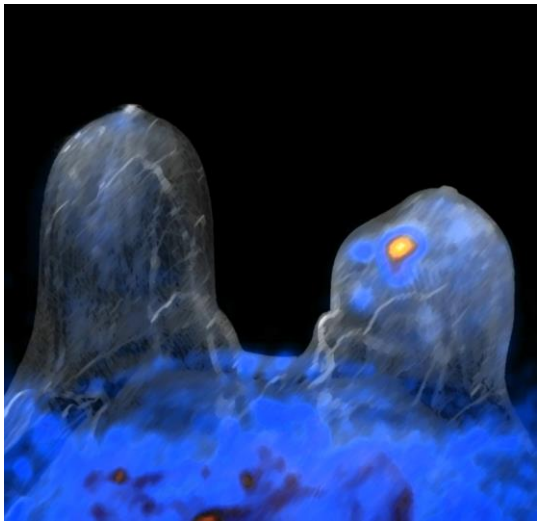
A NEW TYPE OF PET SCAN: [^{11}C]VOROZOLE FOR DETECTION OF AROMATASE IN BREAST CANCER

A Research Study



What is the study about?

This study uses a new type of PET scan to identify areas of the body that are rich in the enzyme aromatase. Aromatase is important for the synthesis of estrogen and is the target of medications used in the treatment of postmenopausal women with breast cancer. Since approximately 70% of breast cancers express high levels of aromatase, this study may lead to the development of a new technique for the early detection of breast cancer.

Your participation in this study will contribute to the many research efforts to fight breast cancer in order to help women like yourself in the future. Please note that this is a research study and not part of the standard medical care for your breast cancer. You should not expect to receive any direct medical benefit from your participation.

You are eligible to participate if:

1. You are a postmenopausal woman who is at least 50 years old or who has had her ovaries removed.
2. You have had a biopsy that is positive for breast cancer.
3. EITHER (a) you are planning mastectomy (single or double) or lumpectomy for treatment of your breast cancer and have not yet undergone surgery;
   OR (b) you are planning to receive chemotherapy prior to surgery;
   OR (c) you have metastatic (stage IV) breast cancer regardless of whether you have had a mastectomy or lumpectomy in the past or plan one now.
4. Patients planning mastectomy or lumpectomy must have had a mammogram in the last 4 months.

What does the study involve?

You will undergo **two** PET scans at Weill Cornell Medical College, located in New York City about 50 miles west of Stony Brook University. A PET scan takes pictures of the body's internal organs using a very low dose of radioactive material called a radiotracer. The radiotracer used in this study is called [^{11}C]vorozole and is designed to accumulate in areas of the body that are rich in aromatase.

Here is an outline of what your day will be like: using a small needle, a nurse will place an intravenous (IV) line in your arm. We will then inject a small amount of the radiotracer into your bloodstream and take pictures using the PET scanner. After the first PET scan is complete, you will be asked to swallow a small pill containing letrozole (Femara™), an FDA-approved medication for breast cancer. Letrozole is very similar to the radiotracer [^{11}C]vorozole but contains no radioactivity. Two hours later, you will receive a second dose of radiotracer and undergo a second PET scan. The PET scan is repeated after letrozole to show that the radiotracer specifically recognizes aromatase and not other substances in the body.

A car service will be provided to bring you from your home to Weill Cornell Medical College where the scans will be performed. The car service will bring you home at the end of the day. You should plan on the study taking all day, approximately 9 hours. You are welcome to bring a companion with you for the day. Lunch will be provided for you and your companion.

Is the study safe?

The study is safe and has been approved by the Institutional Review Board of Stony Brook University and Weill Cornell Medical College. The study involves exposure to a small amount of radiation and a single 2.5 milligram dose of the FDA-approved medication letrozole (Femara™).

The two doses of radiotracer contain about 255 millirems of radiation which is about one-quarter the radiation exposure of a whole body CT scan your doctor may use in regular medical practice. The side effects of the radiotracer are likely to be minor but may be problematic in some patients.

Letrozole, which blocks the activity of aromatase, is approved in the United States for the treatment and prevention of breast cancer in postmenopausal women. This medicine decreases the amount of estrogen which is needed for the growth of most breast cancers. A single dose of letrozole does not cause any significant adverse effects in postmenopausal women whose estrogen levels are naturally low.

Will I receive compensation?

If you complete both PET scans you will receive a $200 volunteer fee as compensation for participation in this research study.

Who is funding the study?

The study is made possible by grants from Brookhaven National Laboratory (BNL) and the National Cancer Institute (NCI), a branch of the National Institutes of Health (NIH).