NCI Community Oncology Research Program – Kansas City (NCORP-KC)

Study Title for Study Participants:

Assessing the Accuracy of Tumor Biopsies After Chemotherapy to Determine if Patients Can Avoid Breast Surgery

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

NRG-BR005: A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment Without Surgery

What is the usual approach to my breast cancer?

You are being asked to take part in this research study because you have received chemotherapy for your breast cancer, and you have not had your surgery. People who are not in a study usually have breast conserving or other surgery after receiving chemotherapy and possibly further therapy if needed. Following your participation in this study, you will have the usual approaches.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer

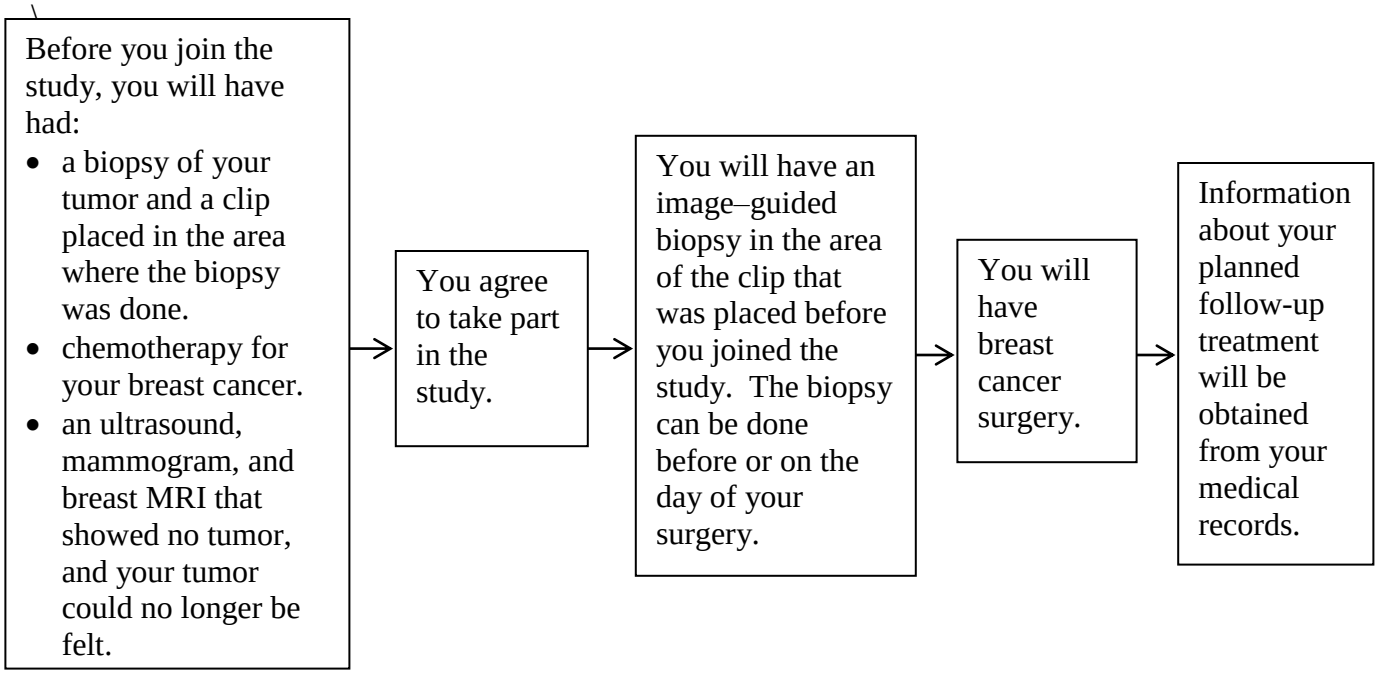
Why is this study being done?

The purpose of this study is to look at tumor tissue collected from a biopsy done before breast surgery to check if the chemotherapy that patients received destroyed their breast cancer cells. The researchers want to learn if it is safe to avoid breast cancer surgery if there are no cancer cells in the tumor sample from the biopsy. In this study, the results of the tumor sample from the biopsy before or on the day of your surgery will be compared to the results of the tumor that is removed during surgery to see if they are the same. If cancer cells are not seen in both the tumor sample from the biopsy and in the tumor removed during surgery, the researchers will use this information to decide if patients who have breast cancer in the future can avoid surgery by using the results of a biopsy. The use of results of a biopsy after chemotherapy to avoid surgery is investigational. There will be about 175 people taking part in this study.

What are the study groups?

Before entering the study, all patients will have received chemotherapy for their breast cancer but will not yet have had surgery. In this study, all patients will have an image-guided biopsy that is done after having received chemotherapy. Some patients will have their biopsy done before the day of their breast surgery and others will have it done on the same day as their breast surgery. Your doctor will discuss the method and timing of your biopsy.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right following the arrows.



Should you choose to take part in this study you will need to:

- Keep your study appointments, and
- Tell your study doctor or study staff about any medications you are taking; any side effects, doctors' visits, or hospitalization that you may have; and if you have been in a research study in the last 30 days or are in another research study now.

How long will I be in this study?

You will have a biopsy either before the day of your surgery or on the day of your surgery. You will be done with this research study after the information about your planned follow-up treatment following surgery is obtained from your medical records.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there is an extra procedure that you will need to have if you take part in this study.

The extra procedure you will have is an image-guided biopsy to collect a sample of tissue from the area of your breast cancer. The tumor tissue will be collected either before you have your breast cancer surgery or the day of your surgery. The samples will be examined for cancer cells as per the hospital's usual standard of care. This biopsy is required in order for you to take part in this study because the research on the biopsy sample is an important part of the study.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that you may:

- Lose time at work or home and spend more time in the hospital or doctor’s office than usual.

- Be asked sensitive or private questions which you normally do not discuss.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.

There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Biopsy risks:

Common side effects of the type of biopsy being used in this research study are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur. Very rarely there may be an accumulation of air in the space that surrounds the lungs causing the lung to collapse, an allergic reaction to local anesthesia, the need for stitches, or damage to a breast implant. Also, you may have some discomfort during the stereotactic biopsy procedure. You will be exposed to radiation similar to radiation from a mammogram. These are the same risks that could have occurred with the biopsy you had to show that you have breast cancer. You may sign a separate consent form before the biopsy is taken. This will be standard surgical consent form from the institution where the biopsy procedure takes place.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. Radiation used in the biopsy procedure could be damaging to an unborn baby. Check with the study doctor about what types of birth control or pregnancy prevention to use while on this study. Tell your doctor if you or your partner becomes pregnant while on the study.

What possible benefits can I expect from taking part in this study?

This study will not help you. It will help researchers collect information that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest.
- If new information becomes available.
- If you do not follow the study rules.
- If the study is stopped by the sponsor, IRB, or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

Neither you nor your health care plan/insurance carrier will be billed for the image-guided biopsy to collect the tumor tissue samples for this study. You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, surgery, and the cost of managing any side effects. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information and/or information about your specimens from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, NRG Oncology
- Alliance for Clinical Trials in Oncology
- ECOG-ACRIN Cancer Research Group
- SWOG

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute (and its agents) in the U.S., and similar organizations if other countries are involved in the study.

If the results of the trial are published, your identity will remain confidential.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

ADDITIONAL STUDIES SECTION

This section is about optional contact for future studies you can choose to take part in.

CONTACT FOR FUTURE RESEARCH STUDIES:

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES **NO**

This is the end of the section about optional and additional studies.

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. this may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. ***[For non-U.S. sites, replace the preceding sentence with "I will be given a signed and dated copy of the form."]*** I agree to take part in the main study and any additional studies where I circled 'yes'.

Print patient's name_____

Patient's signature_____

Date of signature_____

Print name of person(s) conducting the informed consent discussion_____

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____