Breast Cancer Clinical Trial Announcement

The Hoosier Oncology Group (HOG) would like to share information about a clinical trial for people with recently diagnosed locally recurrent or metastatic breast cancer.

Predicting Response and Toxicity in Patients Receiving Chemotherapy for Breast Cancer: A Multicenter Genomic, Proteomic, and Pharmacogenomic Correlative Study

What are Genomics, Proteomics, and Pharmacogenomics and why study them?

Which treatment will work best for me? Unfortunately the only way to answer this question currently is trial and error – try a therapy and see if it works. This is frustrating for both doctors and patients alike. Recent (5 to 10 years) advances in science and technology have given researchers the tools they need to find the answers.

Researchers can now develop pictures of which genes (genomics) and proteins (proteomics) are turned on or off in tumor cells. From this scientists can identify genes and proteins within a tumor that might predict response to a specific chemotherapy. But the same tumor in two different patients may respond differently to the same therapy. Pharmacogenomics studies how drugs act in the body - how slow or fast are they absorbed, distributed and eliminated by the body can effect the response and side effects.

If you participate in this study, you will receive no direct benefit. Information from this study may help other patients in the future by enabling researchers to individualize treatment by predicting which treatment will work best for a patient.

What is the purpose of this study?

This study of about 120 people (40 in each regimen) has several objectives:

- To determine if tumor gene expression (genomics) can tell a patient's response to commonly used chemotherapies.
- To determine if serum (blood) and tumor proteomics can tell a patient's response to chemotherapy
- To determine if drug-specific pharmacogeomics can tell a patient's toxicity and/or response to a specific drugs.

Who is eligible?

Women with local or distant recurrence of breast cancer who:

- have cancer that can be biopsied before treatment begins.
- have enough tissue from the biopsy to be analyzed.
- are planning chemotherapy with one of the regimens listed below.
    - AC (adriamycin/cytoxin)
    - Xeloda
    - Navelbine
    - Gemzar

How is the study designed?

You will not be randomized. You and your doctor will decide what treatment will be best.

Before beginning treatment with one of the 4 regimens listed, you will have samples of tumor tissue, serum (blood) and urine collected.

Collection of the samples will happen at different times during treatment, usually before the next cycle of chemotherapy.

The Hoosier Oncology Group’s collaboration with medical center scientists and community practitioners enables HOG to achieve the goal of treating cancer patients within their own communities, while conducting cancer research studies.

"Center of Excellence for Individualization of Therapy for Breast Cancer."
The project is funded by the Department of Defense Breast Cancer Research Program of the Office of Congressionally Directed Medical Research Programs.