

Breast Cancer Clinical Trial Announcement

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

A Randomized Phase III Trial of Paclitaxel (Taxol) vs. Paclitaxel and Bevacizumab (Avastin) as First Line Therapy for Locally Recurrent or Metastatic Breast Cancer (E2100)

What is Bevacizumab (Avastin) and why add it to Taxol?

Tumors need an increased blood supply in order to grow. The process of growing new blood vessels is called angiogenesis and tumors have the ability to trigger this process. Avastin is a monoclonal antibody (anti VEGF) that can block signals to the blood vessels that tell them to grow. Researchers believe that adding an anti-angiogenesis drug like Avastin to a chemotherapy drug that is known to be effective (Taxol) in women with metastatic breast cancer may be more effective than the chemotherapy drug alone.

What is the purpose of this study?

This study of 685 women has three objectives:

- To determine time to treatment failure of patients who have not had chemotherapy for recurrent or metastatic breast cancer
- To compare objective response rate, duration of response, overall survival, toxicity, and quality of life of women taking T to women taking T+A
- To compare surrogate markers of angiogenesis and response

Who is Eligible?

Women with local or distant recurrence of breast cancer who:

- Are not HER2 positive
- Have not had prior chemotherapy for recurrent breast cancer
- Have not had major surgery within 4 weeks or radiation within 3 weeks
- Do not have a history of clinical significant heart disease
- Are not pregnant

How is the study designed?

Women will be randomized into one of two study arms.

Arm A – Taxol + Avastin

T given every 3 weeks with one week rest
A given the 1st & 3rd week of each cycle

Arm B – Taxol

T given every 3 weeks with one week rest

Quality of Life questionnaire filled out by women in both arms:

- Before treatment begins
- Day 1 of week 17
- Day 1 of week 33

About ECOG

ECOG is one of the largest cancer research organizations in the United States. It has a network of researchers, physicians, and health care professionals at public and private institutions across the country. ECOG conducts clinical trials in all types of adult cancers. It receives funding from the National Cancer Institute (NCI) and other sources. ECOG's goal is to control, effectively treat, and ultimately cure cancer. ECOG provides research results to individuals and the medical community through scientific publications and professional meetings. For more information about ECOG, visit www.ecog.org. For more information about cancer and cancer clinical trials, call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615. You can also visit http://cancer.gov/clinical_trials for clinical trial information and http://cancer.gov/cancer_information for more information about cancer.