Newton-Wellesley Hospital's

Oncology Research News

Newsletter from the Office of Research ■ Summer 2010

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Content:

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Clinical Trial Affiliation with Dana-Farber/Partners Cancer Care

The Office of Research announced that on February 17 Newton-Wellesley was approved as a Clinical Trial Affiliate of Dana-Farber/ Partners Cancer Care. Newton-Wellesley also was recently approved as a Cancer and Leukemia Group B (CALGB) Affiliate. These affiliations will allow us to provide our oncology patients access to oncology studies that are sponsored by Dana-Farber/Partners Cancer Care and also to national studies sponsored by the National Cancer Institute.

This affiliation will be instrumental in meeting the mission of our Oncology Research Program, which is to provide our adult patients and community members access to cutting-edge clinical trials in a state-of-the-art cancer center. The goals of the research program are to advance the understanding, diagnosis, treatment, cure and prevention of cancer and related diseases, increase the survival rates and improve the quality of life for all oncology patients.

The Office directs the human research protection program for Newton-Wellesley. The goal of the program is to oversee research that protects the rights of the research individual, the values of the Hospital and the integrity of the research, while meeting ethical standards and research regulations.

The Office of Research ensures that our clinical research program has the highest quality and protection of the rights and safety of human research subjects. Our research program is accredited through the Association of Human Research Protection Programs (AAHRPP). NWH was among the first 14 programs in the country to be awarded this accreditation and is still one of few community hospitals in the country to have been awarded full accreditation.

REGULATORY REMINDER

CITI Training

All investigators and research personnel participating in the conduct of human-subject research must complete the basic education program developed by the Collaborative Institutional Training Initiative (CITI).

The CITI program is comprehensive and provides case-based learning of ethical concepts and regulations in a web-based learning environment.

The **Basic Course** (for new personnel) is the first course to complete.

Once you have completed the **Basic Course,** all researchers and their staff are required to complete the CITI **Refresher Course** every three years.

Save The Date

HopeWalks

Sunday, September 26, 2010

Check-In: 9:00 a.m. Walk: 10:00 a.m.
Rain or Shine

***HopeWalks* is a 3.5 mile walk to benefit the Integrative Patient Support Services offered at the Vernon Cancer Center. These life-enhancing services help cancer patients through treatment and optimize healing and comfort. We want to make these services available – regardless of a patient's ability to pay.**

***HopeWalks* will start and end at Newton-Wellesley Hospital. There will be a hospitality tent, food, entertainment, prizes, and lots of surprises!**

Join us to send a strong message of HOPE!

For more information, contact Haillie MacNeill at (617) 243-5491

Recently Approved Studies

Randomized phase III trial of weekly paclitaxel compared to weekly nanoparticle albumin bound nab-paclitaxel or ixabepilone, all combined with bevacizumab, as first-line therapy for locally recurrent or metastatic breast cancer.

Aim: To compare the progression-free survival (PFS) with metastatic breast cancer receiving nab-paclitaxel versus paclitaxel (control arm), and to separately compare PFS in patients receiving ixabepilone versus paclitaxel. Treatment will include concomitant bevacizumab in all three arms.

Researchers at New England Hematology/Oncology and Dana-Farber Cancer Institute are collaborating on this study. Drugs used in chemotherapy, such as; paclitaxel, paclitaxel albumin-stabilized nanoparticle formulation, and ixabepilone, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known which treatment regimen is more effective in treating patients with breast cancer.

Partners Protocol: 2010-P-000814

Title: Lymphoma associated with breast implant

Aim: Collaboratively investigators at MGH and NWH are interested in examining patients who have had breast implants and have developed lymphoma. The aim of the study is to assess historical lymphoma data and assess patient outcomes in the historical cases.

For questions regarding clinical trial opportunities contact
Kara Malcolm RN, CCRC at 617-243-5089
kmalcolm@partners.org

Study Highlights

A Prospective Treatment Study for Breast Cancer: Collaboration of New England Hematology/Oncology Associates and The Office of Research at Newton-Wellesley Hospital

Principal Investigator: Dr. Caroline Block

Tykerb Evaluation After CHemotherapy (TEACH) Trial

A Randomized, Double-blind, Multicenter, Placebo-controlled Study of Adjuvant Lapatinib (Tykerb) in Women with Early-Stage ErbB2 Overexpressing Breast Cancer.

Study Aim: The primary objective of the study is to determine whether adjuvant therapy with lapatinib will improve disease-free survival in women with early-stage ErbB2-overexpressing breast cancer.

A focus on breast cancer in young women

A Collaboration of New England Hematology/Oncology Associates and Dana-Farber Cancer Institute

Helping Ourselves, Helping Others: The Young Women's Breast Cancer Study

Study Aim: Breast cancer is the most common malignancy in women in the United States. Young women are not underrepresented in clinical trials, but there are rarely a sufficient number of young women in any trial to draw meaningful conclusions about this subgroup.

Researchers at New England Hematology/Oncology and Dana-Farber Cancer Institute are collaborating on this study that examines breast cancer in young women. We are trying to learn more about how breast cancer in young women affects their lives. We are particularly interested in young women's emotional well-being, fertility concerns, sexual functioning, and physical health and treatment decisions.

For questions regarding clinical trial opportunities contact
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Protocol News

Clinical trials that have patients in follow-up but are no longer enrolling

Breast Cancer

TEACH A randomized, double-blind, multicenter, placebo-controlled study of adjuvant lapatinib in women with early-stage ErbB2 overexpressing breast cancer (TEACH)
Follow-up: Long-term follow-up for disease status and survival. Clinical assessments completed every 12 months for 10 years after study completion or until death, whichever comes first.
Number of patients followed: 10

NSABP B-30 A Three-arm Randomized Trial to compare Adjuvant Adriamycin and Cyclophosphamide Followed by Taxotere; Adriamycin and Taxotere; and Adriamycin, Taxotere, and Cyclophosphamide in Breast Cancer Patients with Positive Axillary Lymph Nodes
Follow-up: Long-term follow-up for disease status and survival. Clinical assessments completed every 12 months until death.
Number of patients followed: 1

NSABP B35 A Clinical Trial Comparing Anastrozole with Tamoxifen in Postmenopausal Patients with Ductal Carcinoma in Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy
Follow-up: Long-term follow-up for disease status and survival. Clinical assessments completed every 12 months until death.
Number of patients followed: 2

ECOG E1199 A Phase III Study of Doxorubicin-Cyclophosphamide Therapy followed by Paclitaxel or Docetaxel Given Weekly or Every Three Weeks in Patients with Axillary Node-Positive or High Risk Node-Negative Breast Cancer
Follow-up: Long-term follow-up for disease status and survival. Every 12 months if patient is > 5 years from study entry.
Number of patients followed: 12

ECOG 2197 Phase III Study of Adriamycin/Taxotere vs. Adriamycin/Cytoxan for the Adjuvant Treatment of Node Positive or High Risk Node Negative Breast Cancer
Follow-up: Long-term follow-up for disease status and survival. Every 12 months if patient is > 5 years from study entry.
Number of patients followed: 7

ECOG C9344 Doxorubicin Dose Escalation With or Without Taxol As Part of the Cancer Adjuvant Chemotherapy Regimen for Node Positive Breast Cancer
Follow-up: Long-term follow-up for disease status, survival status, cardiac disease status. Clinical assessments completed every 12 months until death.
Number of patients followed: 2

ECOG C9741 Phase III Trial of Sequential Chemo Using Doxorubicin, Paclitaxel and Cyclophosphamide or Concurrent Doxorubicin and Cyclophosphamide Followed by Paclitaxel at 14 or 21 Day Intervals in Women w/ Node-Positive Stage II/III Breast CA Local Excision Alone for Selected Patients with DCIS of the Breast.
Follow-up: Long-term follow-up for disease status and survival. Clinical assessments completed every 12 months until death.
Number of patients followed: 1

ECOG E5194 Local Excision Alone for Selected Patients with DCIS of the Breast.
Follow-up: Patients will receive standardized clinical assessments for disease status and survival every 6 months until 10 years, and then annually. Mammographic assessments collected annually.
Number of patients followed: 3

continued

Protocol News

NCCTG N9831 Phase III Trial of Doxorubicin and Cyclophosphamide (AC) Followed by Weekly Paclitaxel With or Without Trastuzumab as Adjuvant Treatment for Women with HER-2 Over-expressing or Amplified Node Positive or High-Risk Node Negative Breast Cancer.
Follow-up: Clinical assessments for disease status and survival yearly for a maximum of 15 years or until disease progression.
Number of patients followed: 10

Colon Cancer:

ECOG C9581 Phase III Randomized Study of Adjuvant Immunotherapy with Monoclonal Antibody 17-1A vs. No Adjuvant Therapy Following Resection for Stage II (Modified Astler-Coller B2) Adenocarcinoma of the Colon
Follow-up: Clinical assessments for disease status and survival every 6 months beginning 18 months after treatment until death.
Number of patients followed: 5

Lymphoma:

ECOG E1496 Randomized Phase III Study in Low Grade Lymphoma Comparing Cyclophosphamide/Fludarabine to Standard Therapy Followed by Maintenance Anti-CD20 Antibody
Follow-up: Clinical assessments for disease status and survival if remission or stable: every 12 months if patient is > 5 years from study entry.
Number of patients followed: 3

SWOG S9704 A Randomized Phase III Trial Comparing Early High Dose Chemoradiotherapy and an Autologous Stem Cell Transplant to Conventional Dose CHOP Chemotherapy Plus Rituximab for CD20 + B Cell Lymphomas (With Possible Late Autologous Stem Cell Transplant) for Patients with Diffuse Aggressive Non-Hodgkin's Lymphoma in the High-Intermediate and High Risk International Classification Prognostic Groups.
Follow-up: Follow-up evaluations will occur every 6 months for 2 years, then annually.
Number of patients followed: 2

Leukemia:

ECOG E1900 A Phase III Trial in Adult Acute Myeloid Leukemia:Daunorubicin Dose-Intensification and Gemtuzumab-Ozogamicin Consolidation Therapy Prior to Autologous Stem Cell Transplantation.
Follow-up: All patients, including those who discontinue protocol therapy early, will be followed for the rest of their lives. The follow-up duration applies from date of registration.
Number of patients followed: 1

Rectal:

ECOG E3201 Intergroup Randomized Phase III Study of Postoperative Irinotecan, 5-Fluorouracil and Leucovorin vs. Oxaliplatin, 5-Fluorouracil and Leucovorin, vs 5-Fluorouracil and Leucovorin for Patients with Stage II or III Rectal Cancer Receiving Either Preoperative Radiation and 5-Fluorouracil or Postoperative Radiation and 5-Fluorouracil.
Follow-up: All patients, including those who discontinue protocol therapy early, will be followed for response until progression and for survival until 10 years from the date of registration.
Number of patients followed: 1