



RESEARCH DEVELOPMENTS at Englewood Hospital and Medical Center

Vol. 2 - Winter 2014

Englewood Hospital and Medical Center continues to expand its clinical research portfolio. Our Investigators are actively pursuing the best treatments available by participating in clinical trials of the next generation of drugs and devices.

Beyond these investigational options for treating a primary disease, EHMC Investigators are also studying new ways to minimize the side effects of standard treatments and to improve our patients' overall quality of life. **This integrative research approach is aligned with EHMC's mission to provide comprehensive, state-of-the art patient services.** As this mission is also driving the new Cancer Treatment and Wellness Center, this edition focuses on our current oncology research projects.

HIGHLIGHT: ONCOLOGY RESEARCH

BRAIN CANCER



"XRT +/- Temozolomide"
Investigator: Dr. Kevin Yao

To determine the best treatment for low-grade gliomas, this study will evaluate **if the addition of a chemotherapy (temozolomide) to standard radiotherapy will improve progression-free survival, overall survival, cognition, and/or quality of life** when compared to radiotherapy alone.

KIDNEY CANCER



"Cabozantinib vs. Sunitinib"
Investigator: Dr. Brian Kim

Targeted therapies have improved the treatment of renal cell carcinoma. Standard first-line therapy is now Sunitinib, a VEGF tyrosine kinase inhibitor. This study is **evaluating if Cabozantinib, a new multiple receptor kinase inhibitor (VEGF/MET), can improve progression free survival** as compared to Sunitinib.

PROSTATE CANCER



"MEAL" Investigator: Dr. Eric Margolis

This study is designed for men with a recent diagnosis of prostate cancer who are under "Active Surveillance." This study aims to **determine if telephone-based dietary counseling will help decrease clinical progression** in these patients. The nutritional counseling is provided free to the study participants.

PANCREATIC CANCER



"S1115" Investigator: Dr. Minaxi Jhawer

Patients with metastatic pancreatic cancer have a median survival of six months. In an effort to identify a new treatment option that can increase overall survival, this randomized study is **comparing the combination of two investigational agents (a MEK inhibitor plus an AKT inhibitor) to the standard mFOLFOX regimen.**

CANCER REGISTRY STUDIES

Despite the strides that have been made in cancer research, there is still much that is unknown. Along with clinical trials to test new treatments, EHMC is participating in several registry studies. These registries are designed to systematically collect the health information of consenting cancer patients. This valuable information is needed by physicians and researchers to gain further understanding of the disease. EHMC has registries open to patients with the following types of cancer:



Chronic Lymphocytic Leukemia - Principal Investigator: Dr. Michael Schleider
Multiple Myeloma - Principal Investigator: Dr. Michael Schleider
Gastrointestinal Cancers - Principal Investigator: Dr. Minaxi Jhawer



BREAST CANCER RESEARCH

As part of the state-of-the-art care provided to all patients in The Leslie Simon Breast Care & Cytodiagnostic Center, our Physician-Investigators are constantly pursuing new strategies in the fight against breast cancer. Our current breast cancer research projects include evaluations of: new diagnostic tools, alternative treatment regimens, and complementary medicine techniques. A few of these ongoing studies are described below:

DIAGNOSTIC

“Spectrosense” Investigator: Dr. Rosalyn Stahl

As featured in the last edition, this study is focused on trying to identify volatile organic compounds (VOCs) in exhaled breath that are associated with breast cancer. The Spectrosense EVA system utilizes a gas chromatographer and proprietary algorithm to detect and analyze the VOCs in collected breath samples. In this phase of the project, interested female patients - both with and without a breast cancer diagnosis - are invited to donate breath samples.



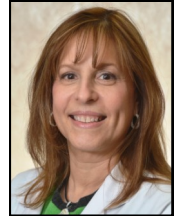
MINIMIZING SIDE EFFECTS

“Testosterone” Investigator: Dr. Jill Morrison

New aromatase inhibitors (AIs) used in the treatment of breast cancer have a therapeutic advantage over the gold standard tamoxifen. However, these AIs have been found to cause joint pain and stiffness in 30-50% of the women taking them, which affects compliance. Data suggests that AIs cause testosterone metabolic anomalies in joint tissues, which may be the origin of this arthralgia. This study is evaluating the ability of subcutaneous testosterone to alleviate these painful symptoms without impeding the efficacy of the AI therapy.

“Suncoast” Investigator: Dr. Jill Morrison

Herceptin (trastuzumab) has been shown to improve overall survival in women with human epidermal growth factor-2 (HER2) positive breast cancers. However, trastuzumab has cardiotoxic side effects that often cause interruption or discontinuation of this effective treatment. Recent studies have shown that ACE inhibitors and beta blockers can prevent anthracycline-induced cardiotoxicity. To determine if one of these medications might also reduce trastuzumab-induced cardiotoxicity, this study is comparing lisinopril (ACE inhibitor) vs. Coreg (beta blocker) vs. placebo in patients receiving adjuvant trastuzumab.



TRIPLE NEGATIVE

“tnAcity” - Investigator: Dr. Jill Morrison

“Triple Negative” breast cancers do not express Estrogen Receptor (ER), Progesterone Receptor (PR), or HER2. As a result, neither endocrine therapy nor Herceptin are effective against these tumors. Due to the reduced number of treatment options available to patients with triple negative disease, this study attempts to identify the best chemotherapy regimen to use as upfront therapy. The study is designed to determine whether a *nab*-paclitaxel (Abraxane) containing regimen will be more effective than the standard gemcitabine followed by carboplatin. Progression free survival, overall survival, and quality of life will all be measured.

“Yoga” - Investigator: Dr. Minaxi Jhawer

Patients with triple negative breast cancer have an aggressive disease course without the option of treatment with hormones or targeted therapies. The incorporation of yoga into the care of these patients may have a positive impact on their overall quality of life. The Triple Negative Breast Cancer Foundation is funding free 10-week yoga programs at EPMC. These yoga sessions are open to all area patients with this diagnosis. In an attempt to measure the impact of the 10-week sessions on quality of life, all participants will be invited to complete pre-yoga (Weeks 1, 2, or 3) and post-yoga (Weeks 8, 9, or 10) questionnaires.





RECENT RESEARCH ACTIVITY

A LOOK BACK AT 2013:

Increased physician membership and expanded infrastructure support helped the EHMC Clinical Research Center record a marked increase in activity during 2013:

Research Subjects registered through the EHMC Clinical Research Center = 230

- Subjects Enrolled onto Registry Studies = 158
- Subjects Enrolled onto Treatment/Intervention Studies = 72

Research Studies approved by the EHMC Institutional Review Board = 39

- Expedited Review Studies = 18
- Full Board Review Studies = 21

In 2013, the most active research departments were: Anesthesiology/Critical Care, Cardiology, Gastroenterology, Oncology, and Vascular Surgery. Many of the studies opened by these groups are still actively recruiting new patients. **Please consider referring your eligible patients or starting a study of interest in your area.** We look forward to continued growth of all EHMC research activities in 2014.

EHMC PUBLICATIONS

The publication of case studies, clinical perspectives, and research activities disseminates new information that can be used by caregivers to improve the treatment of all patients. The following publications are just a few of the recent contributions made by EHMC Investigators to the advancement of medical knowledge:

Gudin, J.A. Assessment of Extended-Release Opioid Analgesics for the Treatment of Chronic Pain. *J. Pain Palliat Care Pharmacother.* 2013 Mar;27(1):49-61.

Cox, J., Roche, S., Gandhi, N. Critical Care Physicians: Attitudes, Beliefs, and Knowledge about Pressure Ulcers. *Adv Skin Wound Care.* 2013 Apr;26(4):168-76

McEvoy, M.T., Shander, A. Anemia, Bleeding, and Blood Transfusion in the Intensive Care Unit: Causes, Risks, Costs, and New Strategies. *Am J Crit Care.* 2013 Nov;22(6):eS1-eS13.

Ozawa, S. Patient Blood Management: Use of Topical Hemostatic and Sealant Agents. *AORN J.* 2013 Nov;98(5):461-78

Orozco-Sevilla, V., Naftalovich, R., Hoffmann, T., London, D., Czernizer, E., Yang, C., Dardik, A., Dardik, H. Epigallocatechin-3-gallate is a Potent Phytochemical Inhibitor of Intimal Hyperplasia in the Wire-Injured Carotid Artery. *J Vasc Surg.* 2013 Nov;58(5):1360-5

Lee, Y.J., Palomino-Guilen, P., Babady, N.E., Lamson, D.L., St. George, K., Tang, Y-W., Papanicolaou, G.A. Disseminated Adenovirus Infection Presenting with Focal Pulmonary Consolidation. *J. Clin. Microbiol.* 2014, 52 (1):350.



THE EHMC CLINICAL RESEARCH CENTER

THE EHMC INSTITUTIONAL REVIEW BOARD

Since 1972, EHMC has had its own local Institutional Review Board (IRB). The purpose of an IRB is to protect the rights of human research subjects. However, the IRB paperwork and review process should not be a deterrent to investigators interested in conducting clinical research projects. The EHMC IRB ensures compliance with all applicable regulations while being both user-friendly and efficient. Whether a retrospective chart review or an industry-sponsored clinical trial, the EHMC IRB staff is available to guide investigators through the entire process. The EHMC IRB is an integral part of our centralized infrastructure that is designed to streamline the conduct of compliant clinical research studies.



The EHMC IRB meets every other month, in January, March, May, July, September, and November. Please contact Renee Lockwood, IRB Coordinator, at 201-894-3852 for upcoming submission deadlines and meeting dates.

NEW INVESTIGATORS

The EHMC Clinical Research Center welcomes the following new Investigators:

- Mindy Goldfischer, MD
- Jonathan Shammash, MD
- Yeon Joo Lee, MD
- Robert Kelley, DO

If you are interested in becoming an Investigator with the Clinical Research Center, please email Jamie.Ketas@ehmc.com or Renee.Lockwood@ehmc.com for information on the required documentation and training.

PUBLIC WEBSITE

This issue of 'RESEARCH DEVELOPMENTS' includes information on just a portion of our ongoing clinical research projects. A full listing of all clinical trials open for patient enrollment is available on our public website: http://www.englewoodhospital.com/ms_clinical-trials_home.asp

This website can also be accessed from the e-Portal. Just scroll down and click on the blue "Clinical Research Center" button that is located on the right-hand side, underneath "Up to Date."

SOCIETY OF CLINICAL RESEARCH ASSOCIATES (SOCRA)

As further evidence of our growing research enterprise, two more members of the EHMC Clinical Research Center have earned the designation of Certified Clinical Research Professional (CCRP). This certification from the [Society of Clinical Research Associates](#) requires both documented research experience and a passing grade on a standardized exam. Meryna Manandhar, Cardiology Research Coordinator, and Jaqueline Takere, PharmD, are both now CCRPs. Congratulations!

If you are interested in learning more about the clinical research opportunities and resources available at Englewood Hospital and Medical Center, please contact the Clinical Research Center at 201.894.3418.



Jamie Ketas
Director, Clinical Research Center
Jamie.Ketas@ehmc.com

