



RESEARCH DEVELOPMENTS at Englewood Hospital and Medical Center

Vol. 3 - Spring 2014

The Clinical Research Center is off to a strong start in 2014. With over 150 subjects already enrolled into research studies this year, EHMC Investigators continue to advance **EHMC's mission to provide comprehensive, state-of-the-art patient services**. In previous newsletters, we have highlighted our Cardiology and Oncology Research Programs; this edition focuses on another area of busy research activity: **Anesthesiology and Critical Care Medicine**. The research studies described below demonstrate the broad portfolio of options available to the EHMC Investigators caring for our most critical patients.

HIGHLIGHT: ANESTHESIOLOGY & CRITICAL CARE

GRAM-NEGATIVE PNEUMONIA

"Amikacin"

Investigator: Dr. Carmine Gianatiempo

Ventilator-associated pneumonia (VAP) represents one of the most common nosocomial infections and a leading cause of death among hospital acquired-infections. In an effort to find another drug to treat VAP, this study is testing an experimental aminoglycoside antibiotic called Amikacin and an innovative delivery system that aerosolizes the study drug so that it is administered directly to the site of infection.

CARBAPENEM-RESISTANT ENTEROBACTERIACEAE (CRE)

"Plazomicin"

Investigator: Dr. Carmine Gianatiempo

CRE causes serious healthcare-related infections in hospitalized patients with other underlying conditions. This study is evaluating an investigational aminoglycoside antibiotic, Plazomicin, to see if it is superior to the approved drug, Colistin, in reducing mortality in patients with bloodstream infections or pneumonia caused by CRE.



OUTCOMES REGISTRY

"Autologous Database"

Investigator: Dr. Aryeh Shander

Studying the past clinical experiences of a patient population can generate the new medical knowledge needed to improve patient care. This registry study collects outcome data on all patients who have had surgery at EHMC and received cell salvage, orthopat, or acute normovolemic dilution. This database serves as a resource to help shape the future of perioperative care.



SEPSIS AND COAGULOPATHY

"ART-123"

Investigator: Dr. Carmine Gianatiempo

Despite significant advances in recent years, mortality from sepsis is still unacceptably high. This randomized, phase III study is designed to determine whether or not the experimental recombinant human soluble thrombomodulin, ART-123, can reduce mortality when given in addition to the normal standard of care treatment for sepsis patients with organ dysfunction and coagulopathy.

BLOOD LOSS DURING SURGERY

"Rainbow Technology"

Investigator: Dr. Aryeh Shander

For surgical patients, hemoglobin concentration is measured to assess blood loss, to determine the need for blood transfusion or other modalities, and as an indicator of overall status. Hemoglobin monitoring is typically done through visual estimates or blood draws. This study is evaluating a non-invasive method, Rainbow Technology, that uses external sensors to calculate hemoglobin concentration according to the hemoglobin's absorption of infrared light.



"PIXEL B"

Investigators:
Dr. Thomas Puzio and
Dr. Seth Perlman



This study is evaluating another novel method to measure blood loss during surgery. This innovative technology utilizes an iPad camera and a proprietary algorithm to try to determine hemoglobin loss based on the color of the blood collected on surgical sponges and in suction canisters.



EHMC PHYSICIAN-INVESTIGATORS

LEADING THE WAY

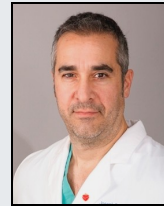
Multi-center clinical trials are the FDA-required path for new drugs, biologics, and devices to be approved for use and marketed to all patients. EHMC Physician-Investigators are participating in many of these clinical trials to contribute to this process, and to provide their patients early access to the next generation of products in a closely-monitored environment. **Due to the dedication of our Investigators, EHMC now ranks among the highest-enrolling sites for several ongoing clinical trials.**

Some of these busy Investigators are highlighted below:

“ABSORB” Principal Investigator: Dr. Joseph DeGregorio

EHMC Ranking: #4 out of 180 total sites

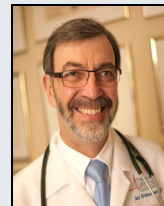
This is a trial of the new ABSORB BVS device, a drug-eluting, bioresorbable vascular scaffold. Since the ABSORB BVS will not be a permanent part of the vessel wall, this novel device may lessen local inflammatory reactions and reduce complications for any future bypass surgery that might be needed.



“REVEAL” Principal Investigator: Dr. Jay Erlebacher

EHMC Ranking: #6 out of 60 total sites

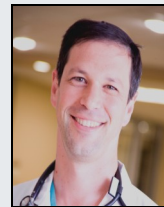
In this study, patients at high risk of developing atrial fibrillation (AF) will receive and be continually monitored by a REVEAL implantable cardiac monitor (ICM). The REVEAL device is then used to detect episodes of AF and to identify incidences that can predict AF onset in these high risk patients.



“ANALYZE” Principal Investigator: Dr. David Feigenblum

EHMC Ranking: #21 out of 89 total sites

This is a trial of a new continuous ST segment monitoring feature available on a standard ICD (implantable cardioverter defibrillator). Patients who are to be implanted with an ICD have the option to have this feature activated and monitored to detect ST shifts as a potential predictor of clinical events.



“ISCHEMIA” Principal Investigator: Dr. Richard Goldweit

EHMC Ranking: #20 out of 228 total sites

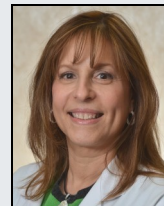
This international study is seeking to establish the standard of care for treating stable ischemic heart disease. Patients with a diagnosis of mild or moderate ischemia are randomized to one of two standard approaches: conservative (medical management) or invasive (cardiac catheterization or bypass).



“BONE PAIN REGISTRY” Principal Investigator: Dr. Jill Morrison

EHMC Ranking: #1 out of 56 total sites

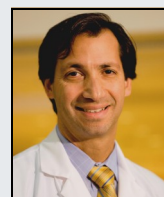
This registry trial is collecting data on breast cancer patients who are starting pegfilgrastim. The most commonly reported side effect of pegfilgrastim is bone pain. This study is designed to estimate the impact of patient education on bone pain in breast cancer patients receiving adjuvant or neoadjuvant chemotherapy with pegfilgrastim.



“CB-183,315 for C DIFF” Principal Investigator: Dr. Mitchell Spinnell

EHMC Ranking: #20 out of 200 total sites

This is a trial comparing the study drug, CB-183,315, to vancomycin for the treatment of Clostridium Difficile Associated Diarrhea (CDAD). The hypothesis is that CB-183,315 will be as effective as vancomycin while being less disruptive to the normal gut flora, thereby reducing the risk of recurrence.





RESEARCH ADVISORY BOARD

The Research Advisory Board continues to meet quarterly to strategize on how best to further increase physician awareness of the growing EHMC Clinical Research Center. At its recent meeting on March 10, 2014, several interested physician-investigators met to discuss recent research activities and venues for outreach.

A Message from the Co-Directors:

In addition to encouraging more physicians to participate in clinical research, the Research Advisory Board, under the leadership of Jamie Ketas, is studying data on the factors that may affect the rate of physician participation. In November 2013, 86 EHMC Physicians responded to a survey about industry-sponsored clinical trials. 41% of respondents indicated that they had previously conducted a clinical trial.

The survey results suggested that previous research experience during Fellowship was an indicator of later clinical trial participation, which may imply that specialists are more likely to participate. Some of the potential deterrents identified were: uncertainty about adequate resources, ethical concerns regarding clinical trial payments to physicians, and lack of access to appropriate trials. The full set of data is currently in preparation for publication, and it will be used by the Research Advisory Board to design targeted recruitment efforts going forward.

Thank you to all of the physicians who participated in the survey; we hope the information gained will lead to additional research growth here at EHMC.

- Drs. Richard Goldweit and Aryeh Shander

ORIGINAL RESEARCH AT EHMC

In addition to their active role in multi-center clinical trials, EHMC Physician-Investigators continue to generate **original, investigator-initiated research projects that are unique to EHMC**. One such project is detailed below:

“Bladder Mapping”

Investigators: Dr. Michael Vardy; Dr. Grant Simons; Dr. Robert Kelley

This first-in-human study is looking at the possibility of adapting the tools and techniques used by cardiac electrophysiologists to help diagnose and treat overactive bladder. The rationale for this approach is based on both the heart and bladder being hollow muscular organs that expand and contract to hold and move fluid. Dr. Robert Kelley, a Fellow working with Dr. Michael Vardy, first drew this comparison and has collaborated with Dr. Vardy and Dr. Grant Simons to design this proof-of-concept study.

In an electrophysiology study looking at cardiac arrhythmia, electrode catheters are used to contact heart tissue. By recording the electrical activity at multiple sites of the heart, the catheter allows for mapping of the electrical activity and the arrhythmia mechanism. With the assistance of Dr. Simons, Drs. Vardy and Kelley will use the same electrode catheters routinely employed for cardiac mapping to contact bladder tissue and map the electrical activity of the bladder. It is hoped that the information gained from this pilot testing may eventually lead to treatment of areas of electrical abnormality in the bladder.





THE EPMC CLINICAL RESEARCH CENTER

THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

Under the direction of Dr. Herbert Dardik and Mr. Thomas Hoffmann, the EPMC Surgical Science and Research Lab utilizes rats for research and teaching protocols. The local regulatory body charged with overseeing this animal use is the Institutional Animal Care and Use Committee (IACUC). At EPMC, the IACUC is administratively housed in the Clinical Research Center. The committee is comprised as per Federal Guidelines to include: unaffiliated members, animal researchers, non-scientists and a veterinarian. The EPMC IACUC is committed to complying with all applicable regulations, ensuring that animals are well cared for, used appropriately, and in minimal numbers. All projects which involve the use of animals must receive IACUC approval prior to initiation.

Future editions of this newsletter will highlight some of the innovative IACUC-approved research being conducted in the EPMC Surgical Science and Research Lab.

NEW INVESTIGATORS

The EPMC Clinical Research Center welcomes the following new Investigators:

• Bernadette Assanah, CRNA	• Vadim Khachaturov, MD
• Norma Barros, RN	• John Perz, MS
• Maria Car, RN	• Joanne Preiss, RN
• Jerome Goldfischer, MD	• Mary Scully, MS
• Tadayuki Kadohira, MD, PhD	• Mikhail Tismenetsky, MD

If you are interested in registering as 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.inglewoodhospital.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."

CLINICAL RESEARCH CENTER

- ✓ Listing of Active Clinical Trials
- ✓ Resources for Physicians

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.



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