



RESEARCH DEVELOPMENTS at Englewood Hospital and Medical Center

Vol. 5 - Fall 2014

The EHMC Clinical Research Center continues to expand its portfolio of exciting clinical research projects. To complement the ongoing studies in Cardiology, Oncology, and other areas highlighted in previous newsletters, the Clinical Research Center is opening new projects in the **Departments of Surgery and Neurosurgery**. The addition of studies in **Podiatry, Vascular Surgery, and Neurosurgery** is further evidence of the growing research enterprise here at EHMC. These activities underscore the Medical Center's commitment to provide innovative, state-of-the-art treatment options to all of our patients.

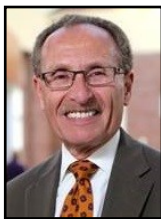
HIGHLIGHT: SURGERY AND NEUROSURGERY

DIABETIC FOOT ULCERS

“Stem Cell Therapy”

Principal Investigator: Dr. Jeffrey Cohen

PDA-002 is a living cell product developed from normal, full-term human placental tissue. This experimental product is being evaluated as a cellular immunomodulator with potential therapeutic benefit. The purpose of this study is to investigate the safety and efficacy of PDA-002 in subjects who have a diabetic foot ulcer and peripheral artery disease. Eligible subjects



will be randomized to one of 4 treatment arms: 3 different doses of PDA-002 and 1 placebo arm. Injections of the assigned treatment will be given on Study Days 1 and 8, and all subjects will be followed for two years.

SPINAL FUSION

“Bone Graft Extenders in TLIF”

Principal Investigator: Dr. Frank Moore

This study will evaluate patient outcomes after transforaminal interbody fusions (TLIF). As part of the TLIF procedure, surgeons can choose from multiple types of bone graft extenders including: stem cells, calcium phosphates, demineralized bone matrix, bone morphogenetic protein and allograft bone preparations. In this study, patients who receive different types of bone graft extenders with the same procedure and interbody device will be compared. Eligible subjects will have their clinical data collected as well as complete pain scales and quality of life questionnaires.



VENOUS LEG ULCERS

“SECURE”

Principal Investigator:
Dr. Steven Elias

Endovenous Laser Treatment (EVLT) of venous disease has been shown to be a clinically effective, less invasive option to open surgery. The Venasure EVLT 400 Micron Fiber Procedure Kit is currently marketed for use in the EVLT of varicose veins. This study will evaluate the safety and efficacy of using this kit for the ablation of incompetent perforator veins (IPV), which is a new indication. Secondary objectives include patient-reported clinical outcomes as measured by pain scales and quality of life questionnaires.



“ACTITOUCH”

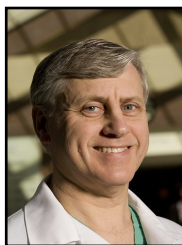
Principal Investigator:
Dr. Steven Elias

Compression therapy is a key part of the treatment for venous leg ulcers. Currently, the most common compression method used is bandaging. This study will test using a device called the ACTitouch to deliver compression therapy. The ACTitouch uses a mechanical pump to compress a sleeve that surrounds the affected limb. The device can deliver either constant or intermittent pressure. This tolerance study is designed to determine patient comfort levels and wound closure rates when using the ACTitouch device.

OTHER SURGICAL STUDIES

“PaciFIST 1 and 2”

Principal Investigator:
Dr. Kurt Wengerter



Both of these investigator-initiated trials are evaluating the effect of a small dose of paclitaxel chemotherapy administered to areas of stenosis that may develop in arteriovenous dialysis access fistulas. PaciFIST-1 is evaluating this new treatment approach in upper arm fistulas and PaciFIST-2 is testing it for the treatment of forearm radial arteries. In both studies, all patients receive the standard of care treatment for any stenotic lesions and then half are randomized to also receive intravascular paclitaxel. The primary objective of these studies is to determine whether this additional step can improve clinical outcomes, including the prevention of restenosis.

“Bariatric Surgery Outcomes”

Principal Investigator:
Dr. Ibrahim Ibrahim



Venous thromboembolism (VTE) is a condition that includes both deep vein thrombosis (DVT) and pulmonary embolism (PE). Recent literature suggests that obese patients may have a lower rate of VTEs than previously reported. This retrospective study will investigate the rate of VTEs in bariatric surgery cases at EHMC to allow for comparison with the published national rate. This information will help to determine whether or not obese patients are at higher risk for VTEs than normal weight patients. Data collected will identify possible gaps in the approach to prevention of VTEs in this population. This study will contribute to the formulation of evidence-based recommendations.

HUMANITARIAN USE DEVICES

A **Humanitarian Use Device (HUD)** is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. The FDA developed this regulation to provide an incentive for the development of devices for the treatment or diagnosis of diseases affecting small populations. The regulation provides for the submission of a **Humanitarian Device Exemption (HDE)** application, which only requires data showing that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use.

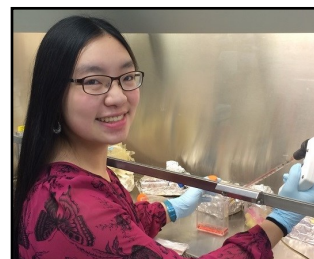
An approved HDE authorizes marketing of the HUD. **However, an HUD may only be used after the Full Board IRB has approved the use of the device for the FDA-approved indication.** Over the years, the EHMC IRB has approved the use of several HUDs at this institution, which allows our physicians to use these devices in the treatment of relatively rare conditions. Below are a few of the HUDs currently approved for use at EHMC:

- ◆ **AVANTA:** Ascension® PIP (Proximal Interphalangeal Joints) and Proximal Interphalangeal Joint (Small Bone Innovations).
Investigators: **Anne Miller, MD and Michael Pizzillo, MD.**
- ◆ **STRYKER:** Neuroform Microdelivery Stent System; Neuroform EX Stent System; Wingspan System with Gateway PTA Balloon Catheter.
Investigators: **Ronald Benitez, MD and Paul Saphier, MD.**
- ◆ **CODMAN & SHURTLEFF:** Enterprise Vascular Reconstruction Device and Delivery System. Investigators: **Ronald Benitez, MD and Paul Saphier, MD.**

SURGICAL SCIENCE AND RESEARCH LAB

Building on the vision of Dr. Herbert Dardik, the expanded Surgical Science and Research Lab continues to generate novel, pre-clinical research through IACUC-approved animal studies. As described in previous newsletters, the local regulatory body charged with overseeing animal use in research is the Institutional Animal Care and Use Committee (IACUC).

As part of EHMC's collaboration with the Bergen County Academies (BCA) and other area high schools, students are trained to assist with, and contribute to, these ongoing projects. One of the current BCA students, **Katherine Chew**, worked with Associate Lab Director, Mr. Thomas Hoffmann, on a project entitled, "Treatment of Influenza-Induced Acute Lung Injury with Iron Oxide Nanoparticles Using an Ischemic-Reperfusion Model." The results from this original research project have been submitted to several academic contests, and while some of the results are pending, Katherine was recently named a national Semi-Finalist in the prestigious Siemens Competition.



By offering this lab facility and housing the IACUC that governs its activities, EHMC is providing a unique and controlled research environment for the community. The Surgical Science and Research Lab continues to have a profound impact on the lives of these students and potentially the future of scientific research and medicine.

RECENT EHMC PUBLICATIONS

Chatterjee S, Bavishi C, Sardar P, Agarwal V, Krishnamoorthy P , Grodzicki T, Messerli FH. Meta-analysis of left ventricular hypertrophy and sustained arrhythmias. <i>Am J Cardiol</i> . 2014 Oct 1;114(7):1049-52.
Garg J, Krishnamoorthy P , Palaniswamy C, Paudel R, Chatterjee S, Ahmad H, Snyder C. Prevalence and predictors of coronary artery disease in adults with Kawasaki disease. <i>Cardiol Young</i> . 2014 Oct 23:1-6
Kadohira T, Schwarcz AI, DeGregorio J . Successful retrieval of an entrapped guide wire between a deployed coronary stent and severely calcified vessel wall using excimer laser coronary artherectomy. <i>Catheter Cardiovasc Interv</i> . 2014 Sep 4.
Krishnamoorthy P , Gupta D, Chatterjee S, Huston J, Ryan JJ. A Review of the Role of Electronic Health Record in Genomic Research. <i>J Cardiovasc Transl Res</i> . 2014 Aug 14.
Shander A , Gernsheimer T. Are we begging a question or begging an answer? <i>Anesth Analg</i> . 2014 Oct;119(4):755-7.
Shander A , Kaplan LJ, Harris MT , Gross I, Nagarsheth NP, Nemeth J, Ozawa S , Riley JB, Ashton M, Ferraris VA. Topical hemostatic therapy in surgery: bridging the knowledge and practice gap. <i>J Am Coll Surg</i> . 2014 Sep;219(3):570-9.e4.
Sharma P , Barajas FJ, Krishnamoorthy P , Campo LM, Blumenthal E, Spinnell M . Transfusion-free Management of Gastrointestinal Bleeding: The Experience of a Bloodless Institute. <i>J Clin Gastroenterol</i> . 2014 Aug 20.



THE EHMC CLINICAL RESEARCH CENTER

CONTINUED GROWTH

The EHMC Clinical Research Center welcomes the following new members:

• Amtul Aala, MD	• Jeffrey Cohen, DPM
• Samantha DelRegno, DPM	• Mary DeRitter, MSO, RN
• Ronnie Kallini, MD	• Eunjung Liliana Kim, MD
• Paul Osemene, DPM	• Damaris Rivera, MS, ANP-BC
• Ritchard Rosen, DPM	• Katy Statler, DPM
• Rico Visperas, DPM	• Chunmei Xie, MD

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

NEW MEMBERS OF THE CLINICAL RESEARCH OPERATIONS TEAM

As the Clinical Research Center grows, the Operations team will expand to support its activities. Two new research study coordinators have recently joined the team, and are working hard to facilitate the continued expansion of EHMC research activity:

- **Michael Sohn** is working with the Medical Oncologists and is focused on the Oncology Research Program.
- **Patricia Miseses** will concentrate on the new Wound Healing Center studies, and assist with other areas as needed.

PUBLIC WEBSITE - UPDATES ARE ON THE WAY...

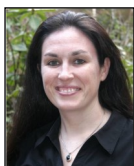
The Clinical Research Center's public webpage is slated for an upgrade in the coming weeks. In the interim, details on available resources, summaries of our active clinical trials, and contact information are still available at: http://www.EnglewoodHospital.com/ms_clinical-trials_home.asp

CLINICAL RESEARCH CENTER

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

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

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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ENGLEWOOD
HOSPITAL AND MEDICAL CENTERSM
AN AFFILIATE OF MOUNT SINAI SCHOOL OF MEDICINE