Welcome

Welcome to the Carle Research Newsletter! The purpose of this newsletter is to inform you of the various research and scholarly activities occurring on the Carle campus. We hope to highlight various items such as investigator profiles, specific research studies and activities, publications, IRB and regulatory updates, and much more. We want you to become aware of the wonderful and exciting research activities that are ongoing at our institution and plan to provide this newsletter on a quarterly basis.

Carle Foundation Hospital and Carle Physician Group actually have a long history of research activities dating back to the 1960s with Carle radiologist Cesare Gianturco, MD who invented the Gianturco-Roubin coronary stent and the Gianturco coil. Carle Clinic at that time believed Carle should fund research of the “theory-and-therapy” type. Since then many Carle physicians and healthcare providers have completed meaningful research projects and contributed medical publications. Carle Foundation Hospital created a research department in 1980 headed by Ralph Nelson, MD, PhD a nationally known expert in the area of nutrition and metabolism. Researchers at the Carle Cancer Center since 1976 have provided access to clinical trials to thousands of cancer patients and contributed hundreds of publications and abstracts to the medical literature. Most recently nursing research has also contributed to the advancement of nursing and medical knowledge at Carle and was instrumental in the hospital achieving Magnet status in 2009.

Currently Carle healthcare providers are involved in more than 300 research studies and scholarly activities. The activities range from investigator-initiated studies to pharmaceutical and medical device studies. Research at Carle encompasses six main areas: cancer research, translational research, investigator-initiated studies with both physicians and non-physicians, clinical trials, nursing research, and Graduate Medical Education research and scholarly activity. The establishment of the Carle Research Institute and the continued significant research through clinical trials in oncology only further demonstrates Carle’s commitment to maintaining its contribution to the advancement of medicine and nursing. We hope you enjoy learning about the important research and scholarly activities happening at Carle!

Sincerely yours,
Charles E. Sanders Jr., MD
Vice President of Research & Chief Academic Officer
CLINICAL TRIALS UPDATE

As of June 21, Carle has enrolled 46 subjects in the “TRANSLATE-ACS” study. Nationwide, the study plans to enroll 17,000 subjects who will receive four follow-up phone calls by Duke Clinical Research Institute over a period of 15 months. Enrollment is expected to extend into 2012. Dr. Matthew Gibb is the principal investigator and is supported by sub-investigator Dr. Sanjay Mehta and staff from clinical trials and cardiac cath lab.

The primary objective of this observational study in heart attack patients treated with PCI (a procedure in which a narrowed section of the coronary artery is widened) and prescribed antiplatelet therapy (such as Plavix or Effient) is to compare Effient to other ADP receptor inhibitor therapy on all-cause death, MI, stroke, or unplanned coronary revascularization through 12 months.

Dr. Gibb says this study is important because it is “real world.” The study follows the institution’s own “standard care.” Dr. Gibb hopes the study will answer questions about antiplatelet therapy taken chronically after cardiac interventions. The study is also looking at the intensity of antiplatelet use. Is a lower dose just as good as a higher dose? “It’s a big deal,” says Dr. Gibb, since cardiology gets 10-15 calls per week from patients asking what they should do about their Plavix (or Effient) because they need to go off their medication for a procedure or surgery, and that can be a concern. Others simply can’t afford the medication. Some patients have no insurance or low coverage, and the cardiology nurses spend an enormous amount of time working with the assistance programs with limited success. Dr. Gibb hopes the study will demonstrate that patients may be able to take the antiplatelet therapy for a shorter time period.

Site-specific quarterly reports include information such as the subjects’ adherence to their cardiac medications and rehospitalizations. This information for Carle is also compared to “like hospitals” and to “all study sites,” which allows Dr. Gibb to see how our subjects compare with other institutions.

INVESTIGATOR PROFILE: DR. MATTHEW GIBB

Dr. Matthew Gibb joined Carle Clinic in 1994. He is board certified in internal medicine, interventional cardiology and cardiovascular disease. He received his undergraduate degree from Dartmouth College and his medical degree from St. Louis University. He has staff appointments at Paris Community Hospital, Carle Foundation Hospital, St. Anthony Memorial Hospital and Provena Covenant Medical Center. He has medical/research interests in interventional cardiology, ischemic heart disease, percutaneous treatment of peripheral vascular disease and cardiac risk factor modification.

Dr. Gibb is a HealthGrades five-star Doctor at Carle Foundation Hospital in cardiac care, coronary intervention procedures and medical diagnosis. In addition, he is a Navy-experienced pilot, likes antiques, is an avid bicyclist and has a home in New Hampshire by the lake where he goes to relax.

PUBLICATIONS

CARLE IRB - NEW RESEARCH STUDIES

KAATSU training, muscle strength, and inflammation in chronic kidney disease patients
PI - Ken Wilund, PhD

Improving heart failure outcomes
PI - Kristin Pritts, RN

Sudden sensorineural hearing loss: a retrospective review
PI - Michael Novak, MD

Cancer related outcomes in patients treated with angiotensin receptor blockers
PI - Poonam Velagapudi, MD, MS

Awareness of deficits in persons with traumatic brain injury
PI - Brenda Wilson, PhD

Community awareness plan for planned emergency research
PI - Charletta Little, BS

Angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers: effect on ablation outcome in atrial fibrillation
PI - Poonam Velagapudi, MD

Does phlebitis or infiltration increase if intravenous catheter dwell time is increased to 96 hours and if phlebitis or infiltration does occur what is the cause
PI - Andrea Keeton, RN

Continuous furosemide-mannitol infusion versus continuous furosemide infusion in patients hospitalized for heart failure
PI - Jean Holley, MD

Does a systematic education class on using the Situation/ Background/ Assessment/ Recommendation (SBAR) procedure improve the nurses' ability to utilize the SBAR tool
PI - Deborah Davis, RN

S.O.C.K. communication initiative: enhancing clinician-patient communication to increase patient satisfaction
PI - Adam Johnson, MPT

Local worlds and transnational medicine: how clinical realities, ethical dilemmas, and physician relationships are impacted by local meanings and arrangements and global standards of care and technology
PI - Michael Kral, PhD

Will systemic education on proper documentation of the pain assessment in advanced dementia (PAINAD) scale improve pain control interventions for demented patients by registered nurses on a medical/surgical floor
PI - Erica Halcomb, RN

Effects of early implantation on spoken language development in children with hearing loss
PI - Jean Thomas, MS, CCCA

WHO’S LOOKING OUT FOR RESEARCH SUBJECTS AT CARLE

Researchers at Carle are currently involved in more than 300 studies. These research activities are a collaboration of investigators and research personnel along with individuals who volunteer their time and energy as research subjects. So, who else looks out for these subjects who make Carle research possible?

Institutional Official (IO): The IO is ultimately responsible for ensuring that research at Carle complies with federal regulations protecting research subjects. The IO guarantees that Carle maintains a human subjects protection program with enough resources to perform its duties. The IO also serves as the institutional contact with federal agencies like the Office for Human Research Protections and the U.S. Food and Drug Administration. Bruce Wellman, MD and Carle Physician Group CEO, is Carle’s IO.

Human Protections Administrator (HPA): At Carle, the HPA reviews all reports of subject complaints, adverse events, or potential noncompliance. The HPA also oversees study investigations initiated by an Institutional Review Board (IRB) or IO. Our HPA—Rebecca Morgan-Boyd, PhD—is part of the Compliance office, so she is well-versed in the regulations protecting human subjects.

Human Subjects Protection (HSP) Office: The HSP office works in day-to-day support of the Carle IRB. The HSP office handles administrative issues, reviews research proposals, answers calls from investigators and research subjects, and conducts educational activities to inform investigators of ways in which to ethically conduct research. The office consists of a manager, Kyle Galbraith, PhD; a specialist, Molly Caldwell, MSW, LCSW; and an office coordinator, Mary Lyman, AAS.

Institutional Review Board (IRB): The Carle IRB is an independent group of 10 individuals, including a physician, pharmacist, nurse, chaplain and members of the Champaign-Urbana community. The IRB reviews research studies at Carle to ensure adequate protections are in place regarding the rights and welfare of research subjects. Their diverse background means that research projects are thoroughly vetted before taking place. Research activities involving human subjects must be approved by the IRB before an investigator can begin the project.

For more information regarding research at Carle, please visit carle.org/research.
CARLE-UNIVERSITY OF ILLINOIS COLLABORATIONS

Carle research has a long-standing relationship with the University of Illinois (Illinois). In 2009 we dedicated a physical space for Illinois researchers and Carle clinicians to work together on cutting edge translational research. The Biomedical Research Center, located on the third floor of the Mills Breast Cancer Institute, is over 25,000 square feet of bench research space, cell culture rooms, and research offices. Currently it houses the University of Illinois Division of Biomedical Sciences staff, professors Steve Boppart and Rohit Bhargava’s research laboratories, Carle Research Institute staff, and the research laboratories of Carle MDs John Aucar and Partha Ray.

In the general area of translational research we have 20 active studies. Here are three examples of ongoing collaborative research:

- I Kids-Illinois Kids Development Study: Illinois - Susan Schantz, PhD; Carle - Gail Kennedy, MD
- Coherent Optical Detection of Middle Ear Disease: Illinois - Stephen Boppart, MD, PhD; Carle - Michael Novak, MD
- Pilot Study: The Microbial Landscape of Colorectal Cancer: Illinois - H. Rex Gaskins, PhD; Carle - John Aucar, MD

CANCER RESEARCH UPDATE

The results for the ExCel study were released during the recent American Society of Clinical Oncology meeting held in Chicago, Ill. in June. Carle participated in this international and multicenter study led by the National Cancer Institute of Canada Clinical Trials Group, which was a double-blind randomized phase III study for 4560 postmenopausal women who were at increased risk of developing breast cancer. The study showed that exemestane (Aromasin), an aromatase inhibitor, significantly reduces the risk of invasive breast cancer by 65% compared to the placebo.

The Carle principal investigator, Kendrith Rowland, MD, and his research team enrolled 79 women in the ExCel study. With such positive results, Carle investigators decided to make the optional component of the ExCel study available at Carle. This will allow women who were assigned to the placebo group of the ExCel study to “cross over” and receive up to five years of exemestane. This is only offered to women who are currently on or recently received the placebo. Women who are already assigned to exemestane will remain on the drug for the complete five years of the study.

Research Personnel Picture Key


Not pictured: Bobbi Hodge; Bre Stillwell, BS; Brian Moses, BS, CCRP; Carly Halberstadt, BS; Christie Rogers, BS, CCRP; Christine Canfield, BS, CCRP; Darcie Reckers, BS; David Graham, MD; Kendrith Rowland, MD, Melissa Phillips, RN, MHA, OCN; Pam Woo; Pamela Talbott, MPA; Pauline Mbuvi, MS, CCRP; Rachel Magasin, MD; Shelly McCaskill, AS; William Schuh, MD, PhD, MBA

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