Spotlight on Clinical Research

Heart Failure, Lipoprotein & Major Cardiovascular Events, Alzheimer's Intervention

Heather Madara
Clinical Research Coordinator
Roy S. Small, M.D.
Medical Director of Clinical Research
Penn Medicine Lancaster General Health Research Institute


Small


Madara

Editor's note: *This is the 10th in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. Other active studies have been described in previous issues of this Journal. The Research Institute wishes to recognize two first-time PIs included in this article: Dr. Robert Donovan (AT HOME-HF) and Dr. Marjan Mujib (HORIZON).*

Physicians who wish to refer patients for any of the studies mentioned below are encouraged to contact the Penn Medicine Lancaster General Health Research Institute at 717-544-1777.

Other members of the Penn Medicine LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH at 717-544-8004.

SPONSORED STUDIES

AT HOME-HF: Avoiding Treatment in the Hospital with Furoscix for the Management of Congestion in Heart Failure — A Pilot Study

Sponsor: scPharmaceuticals
Principal Investigator: Robert Donovan, M.D.

This heart failure pilot study from scPharmaceuticals aims to determine the safety and effectiveness of a novel formulation of furosemide, which can be administered subcutaneously as an outpatient via the Furoscix On-body Infusor. This Furoscix infusion system delivers continuous outpatient supplemental subcutaneous furosemide as an alternative to inpatient intravenous infusion.

Eligible patients have documented chronic heart failure and fluid overload. During the treatment phase of the trial, participants and/or their caregivers receive training on how to administer the injection on their own outside of the clinical setting. The study team monitors participants via clinic visits and phone calls during the 7-day treatment phase. During the participants' 30-day study involvement, the study PI can determine if participants should receive additional doses of study drug after the initial dose.

Enrollment and eligibility screening take place concurrently while the patient is at the clinic. Because of the time commitment required and the novelty of the drug administration, the study has a total enrollment goal of 51 participants across approximately 20 sites. LGH plans to enroll up to three (3) participants.

HORIZON: Assessing the Impact of Lipoprotein (a) Lowering With TQJ230 on Major Cardiovascular Events in Patients With CVA

Sponsor: Novartis Pharmaceuticals
Principal Investigator: Marjan Mujib, M.D.

HORIZON is the follow-up study to the Heritage study, also sponsored by Novartis Pharmaceuticals. Heritage, an epidemiological study conducted at LGH in the Spring of 2020, established the patient pool of individuals with CVD and elevated Lp(a). Currently, there is no approved treatment to lower Lp(a) even though it is a risk factor for CVD that is widely tested for.

The HORIZON study is a randomized, double-blind, placebo-controlled phase 3 trial being conducted at over 600 sites. It aims to determine if the study drug, TQJ230 or pelacarsen, effectively lowers levels of Lp(a), as well as lowering the risk of CV death and MI.

Study participants agree to remain involved in the study for a minimum of 2.5 years and a maximum of 4 years. Their participation includes monthly subcutaneous injections of either the study drug or placebo, as well as regular follow-ups with the study's doctor and research team.

BMAD HF: Benefits of Microcor in Ambulatory Decompensated Heart Failure

Sponsor: Zoll Medical Corporation
Principal Investigator: Lisa Rathman, CRNP

The aim of this study is to determine if the μCor Heart Failure and Arrhythmia Management System aids in decreasing the number of hospital admissions and heart failure-related deaths in the heart failure population. Heart failure patients have a propensity to retain fluid, and this monitoring system allows providers to continuously compare patient symptoms to an objective transcutaneous measurement of intrathoracic fluid volume. Study participants wear the μCor System for up to 90 days during which time they complete a daily diary of their symptoms and heart failure events, and participate in weekly phone calls with the study team. Study participants also meet with the study provider every 30 days in the clinic for more thorough assessments.

BMAD HF began enrollment at LGH in December 2020. At this writing, the research team has enrolled three (3) participants, with plans to enroll a total of 25.

Reducing Disability via a Family-centered Intervention for Acutely-Ill Persons with Alzheimer's Disease and Related Dementias

Led by: Penn State University, College of Nursing
Grant-Funded by: National Institute of Health
Local Investigator: Katrina Fetter

Hospitalization often provokes increased confusion and functional decline in patients diagnosed with Alzheimer's disease and related dementias (ADRD). This NIH-funded project seeks to determine if training family caregivers on how to best care for their family member with ADRD improves the patient's outcome and level of dependency. Family members who participate in the study receive training by the study team, and work with the nurses on the floor to determine the best next steps in the care of their family member.

This approach, Family-centered Function Focused Care (Fam-FFC), partners family caregivers with nurses to improve education and understanding of how best to care for family members with ADRD. The study is divided into two arms: Family-centered Function Focused Care (Fam-FFC) and Attention Control (Fam-FFC Ed-only). Every family caregiver in the study receives training on best practice in managing their family member's condition. The Fam-FFC arm includes training a Nurse Champion on the floor who implements the study, training nursing staff, educating the family caregiver and the patient, and following up with the caregiver, patient, and nursing staff to understand the efficacy of the approach. Those randomized to the Attention Only arm work with nursing staff trained on the study and learn how to best care for and support their family member with ADRD.

This study is being conducted in collaboration with Penn State University's College of Nursing. The Penn State research team manages the consenting, training of the nursing staff at LGH, and data collection, while the LGH team works directly with the caregivers and patients. Currently, more than 100 individuals are enrolled in the study at LGH including family caregivers, patients with ADRD, and nurses on the hospital floor.

Heather Madara
Penn Medicine LG Health Research Institute
131 E. Frederick St.
Lancaster, PA 17602
717-544-1777
Heather.Madara@pennmedicine.upenn.edu

Roy S. Small, M.D.
The Heart Group of Lancaster General Health
217 Harrisburg Ave.
Lancaster, PA 17603
717-544-8300
Roy.Small@pennmedicine.upenn.edu