

SPOTLIGHT ON CLINICAL RESEARCH

Software to manage COPD, an ablation system for atrial flutter, care model for OUD patients

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 ninth 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.

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 LGH 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

LINQ for COPD: Medtronic LINQ™ for Chronic Obstructive Pulmonary Disease (COPD)

Sponsor: Medtronic

Principal Investigator: Shakeel Amanullah, MD

In this non-randomized, observational, pre-market research study, patients with frequent exacerbations of Chronic Obstructive Pulmonary Disease (COPD) receive the FDA-approved Reveal LINQ™ device with investigational software (LINQ™-HF RAMware).

The software collects physiologic data, such as impedance and temperature, which may predict COPD exacerbations.

The study aims to examine these physiologic parameters to see if they can predict health care utilization and exacerbation events in this group of COPD patients.

Eligible participants interested in the study agree to the device implant, follow-ups, and data collection spanning approximately 12 months. This is the first research study conducted in collaboration with Pulmonary Associates of Lancaster. The sponsor, Medtronic, aims to enroll up to 100 participants across U.S. sites. LGH plans to enroll up to 20 participants, with 3 already enrolled.

AcQForce Flutter: AcQBlate Force Sensing Ablation System US IDE for Atrial Flutter Mutation

Sponsor: Acutus Medical Inc.

Principal Investigator: Matthew Bernabei, MD

Previous research studies on atrial flutter led to the development of ablation techniques, medications, and other devices. The purpose of this prospective, non-randomized study is to determine the safety and effectiveness of the investigational study device, AcQBlate Force Sensing Ablation System.

This system includes the AcQBlate Force Sensing Ablation Catheter (AcQBlate® FORCE), the Qubic Force® Sensing Module (Qubic Force), the Qubic Radiofrequency (RF) Generator, and the Qiona Irrigation Pump with Tubing Set.

The sponsor, Acutus Medical, specializes in arrhythmia management.

This system will better enable them to evaluate ablation management of symptomatic cavotricuspid isthmus dependent atrial flutter. Eligible participants will have had at least one documented episode of typical AF within the past 6 months in addition to being clinically indicated for de novo catheter ablation. Participants who consent to participate receive the ablation system and complete comprehensive

follow-up with data collection to ensure safety and effectiveness.

LGH plans to enroll 10-20 participants locally, with a study-wide enrollment goal of 100 participants across all sites around the world. This study is expected to begin enrollment in late April or early May of 2021.

The Whole Health Study: Collaborative Care for Opioid Use Disorder and Mental Health Conditions

Led by: University of Pennsylvania Perelman School of Medicine

Grant-Funded by: National Institute of Mental Health

Local Investigator: Caroline Barnhart

The Behavioral Health program at Penn Medicine LGH is working together with the University of Pennsylvania Perelman School of Medicine (UPenn) on a collaborative care model for patients with opioid use disorder (OUD) along with depression, anxiety disorder, or post-traumatic stress disorder (PTSD).

While mental health providers have historically used collaborative care as an effective treatment model, individuals with OUD do not always receive that same treatment. This study aims to improve upon previous models, and will develop an effective collaborative care model with a team-based approach for this unique group of patients.

The study consists of three groups:

1. Augmented Usual Care (AUC) - this group of participants receives standard of care support from their PCP.

2. Collaborative Care (CC) - this group receives a care manager with specialized training in treating individuals with OUD and mental health conditions. They also continue to receive their standard PCP care.

3. Collaborative Care Plus (CC+) - this group receives standard PCP care, a care manager, and the support of a Certified Recovery Specialist (CRS). These specialists may share similar experiences with the participants and act as a connection to the community and to those in recovery.

In addition to evaluating patients, the study also plans to evaluate providers using self-reporting data collection via REDCap.

LGH's role is to provide potential participants, and to support the UPenn team in the study's implementation.

Over the past year, LGH and UPenn have worked together on a number of research projects, and this cooperation enables both research programs to expand their resources and expertise. It is exciting to envision what the future will hold as this partnership develops.

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