

Studies in the Division of Cardiothoracic Surgery

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Editor's note: This is the 15th 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 a first-time principal investigator included in this article, Dr. Jeremy McGarvey (LeAAPS) from Cardiothoracic Surgery.

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

LeAAPS: Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction Trial

Sponsor: AtriCure

Principal Investigator: Jeremy McGarvey, MD

It is already known that closing the left atrial appendage during open heart surgery helps reduce the risk of stroke and embolism in patients with atrial fibrillation (AF). The goal of the LeAAPS trial is to examine if this intervention will prevent future strokes in patients who have risk factors for AF but have not been diagnosed with the condition.

This trial is a prospective, randomized, blinded, superiority trial being conducted at over 200 sites worldwide. The objective of this trial is to evaluate the effectiveness of left atrial appendage exclusion for the prevention of ischemic stroke or systemic arterial embolism in subjects undergoing cardiac surgery who have risk factors for atrial fibrillation and ischemic stroke. The AtriClip is FDA approved for use in patients with AF, but the use of it in patients without diagnosed AF is investigational.

Eligible patients are randomized to either receive the atrial clip or to not receive the atrial clip during open heart surgery. The study team collects data at reg-

ular intervals post procedure to determine safety and efficacy. Participants can expect their participation to last for about five years from enrollment to study end.

Lancaster General Health plans to enroll 100 patients into the study, with seven already enrolled at the time of this article.

EVOLVE-MI: A Pragmatic Randomized Multicenter Trial of Evolocumab Administered Very Early to Reduce the Risk of Cardiovascular Events in Patients Hospitalized with Acute Myocardial Infarction

Sponsor: Amgen

Principal Investigator: Marjan Mujib, MD

EVOLVE-MI is a randomized, multicenter trial sponsored by Amgen. The study compares the addition of evolocumab (a PCSK9 inhibitor) to standard lipid therapy in patients hospitalized with an acute coronary syndrome (ACS). The sponsor aims to evaluate the effectiveness of evolocumab specifically in patients hospitalized with non-ST-segment elevation myocardial infarction (NSTEMI) and ST-segment elevation myocardial infarction (STEMI).

Effectiveness will be determined by the percentage change from baseline LDL-C, total myocardial infarction events, total arterial or coronary revascularization procedures, total ischemic strokes, time to first and total events related to MI, and time to all-cause mortality.

The study plans to enroll about 4,000 participants across all sites. Lancaster General Health plans to enroll 14 participants, with nearly half of that goal already enrolled at the time of this article.

CLASS-HF: Consistently Assess Signs and Symptoms of Heart Failure

Funded by: Abbott

Lead Site: Illinois State University

Principal Investigator: Lisa Rathman, CRNP

This investigator-initiated study is the result of a collaboration across four institutions: Illinois State

University (lead site), University of Colorado, University of North Carolina at Greensboro, and Penn Medicine Lancaster General Health.

Evaluating the functional class of heart failure for patients is a highly subjective process based upon the provider's impression of the patient's physical limitations. The study investigators created an NYHA Classification Guide in an effort to establish a more reliable and accurate assessment of functional class.

Eligible heart failure patients will have their functional class assessed using the NYHA Classification Guide. Separately and without awareness to the result of the provider's assessment, the participant will complete a six-minute walk test (6MWT) using the "gold standard 6MWT." Accuracy of the NYHA Classification Guide will be assessed by comparing the provider's functional class determination and the result of the 6MWT.

More than 100 participants will be enrolled across the four sites in this part of the study, with approximately 30 participants being enrolled at LG Health.

In the subsequent part of the study, interested providers will be recruited to utilize the NYHA Classification Guide for 30 days. At the end of the 30-day

period, they will communicate via survey any barriers to implementation, along with its effectiveness and usability to the study team. This part of the study will inform the study team on the ease of implementation of the NYHA Classification Guide.

A total of three providers will be involved in this part of the study, and LG Health plans to enroll 10 providers.

Active Clinical Studies at Lancaster General Health

A complete list of active clinical studies at Lancaster General Health is available online. To access the most current list, scan the QR code, or find the link on the Resources/Links page at JLGH.org. To make a referral to any study on the list, call the Penn Medicine Lancaster General Health Research Institute at 717-544-1777.



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