Hypertrophic Cardiomyopathy, Ischemic Stroke, Heart Failure

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Editor's note: This is the 18th 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 Research Institute at 717-544-1777. Other members of the 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

OCEANIC-STROKE: Phase 3 Study to Investigate the Efficacy and Safety of the Oral FXIa Inhibitor Asundexian (BAY 2433334) Compared with Placebo in Participants after an Acute Noncardioembolic Ischemic Stroke or High-Risk TIA

Sponsor: Bayer
Principal Investigator: Danielle Cross, MD

OCEANIC-Stroke is a randomized, multicenter trial sponsored by Bayer aimed at identifying a better preventative approach to ischemic stroke. The main purpose of this study is to learn whether asundexian, a novel anticoagulant, works better than placebo at reducing ischemic strokes in participants who recently had a noncardioembolic ischemic stroke or temporary stroke-like symptoms when given in addition to standard antiplatelet therapy. It aims to further improve the standard of care with regard to the risk of bleeding.

Participants are randomized to either take oral asundexian or placebo once a day for a treatment period that ranges from at least three months and up to 31 months. Study participants will have follow-up visits approximately every three months during the treatment period via either a phone call or a visit to the study site.

This study will take place in over 30 countries and seeks to enroll more than 9,000 participants. The study team at LG Health, led by Dr. Danielle Cross, plans to enroll about 25 participants locally.

DISCOVER-HCM: Deliver Insights in Hypertrophic Cardiomyopathy and Observational Outcomes in Real World — United States Prospective Registry Study

Sponsor: Bristol Myers Squibb
Principal Investigator: Arpan Patel, DO

This observational registry aims to understand the safety and effectiveness of various medications used in treating symptomatic obstructive hypertrophic cardiomyopathy (HCM). HCM causes focal cardiac muscle thickening, which can obstruct outflow and/or cause valve dysfunction. This registry will also evaluate the impact of these medications on participants' quality of life.

The research team collects information about eligible participants and their condition from their medical records during a five-year period. Participants also complete surveys about their quality of life every three months. Study participation does not require any extra visits to participants' doctors' offices.

LG Health plans to enroll 20 patients into the registry, with nine already enrolled at the time of this article.

PACeS: Anticoagulation for New-Onset Post-Operative Atrial Fibrillation after CABG

Funded by: National Heart, Lung, and Blood Institute
Principal Investigator: Mark Epler, MD

Providers may prescribe anticoagulants or antiplatelet agents to prevent blood clots in patients with post-operative atrial fibrillation (POAF). The primary objective of this prospective, open-label, randomized study is to evaluate the effectiveness (prevention of thromboembolic events) and safety (major bleeding) of adding oral anticoagulation (OAC) to background antiplatelet therapy in patients who develop new-onset POAF after isolated coronary artery bypass graft (CABG) surgery.

This trial randomizes participants (1:1 ratio) to receive OAC (intervention arm) or no OAC (control

arm). They will follow their treatment plan for a 90-day period. Follow-up visits will take place at 90 days (site visit) and at 30, 60, and 180 days (phone call).

The primary effectiveness endpoint is the composite of death, ischemic stroke, transient ischemic attack, myocardial infarction, systemic arterial thromboembolism, or venous thromboembolism at 90 days after randomization. The primary safety endpoint is BARC (Bleeding Academic Research Consortium) grade 3 or 5 bleeding at 90 days after randomization. The overall intent is to evaluate the trade-off in prevention of thromboembolic events versus an increase in bleeding.

Any eligible patients who choose not to participate may enroll in a parallel registry instead. The study team will document patients' baseline risk profiles and treatment strategies in terms of anticoagulants or antiplatelets received. These patients will also be asked to fill out a brief decliner survey.

LG Health was invited to join this study alongside the University of Pennsylvania. Dr. Mark Epler of Cardiothoracic Surgery at LG Health is the local principal investigator working with the study team to enroll about 40 participants.

HERMES: Effects of Ziltivekimab Versus Placebo on Morbidity and Mortality in Patients with Heart Failure with Mildly Reduced or Preserved Ejection Fraction and Systemic Inflammation

Sponsor: Novo Nordisk
Principal Investigator: Amit Varma, MD

The HERMES study is an interventional, randomized, double-blind study designed to evaluate the effects of ziltivekimab versus placebo. Previous studies demonstrated that ziltivekimab, a therapeutic monoclonal antibody delivered subcutaneously, can lower inflammation and have a positive effect on heart failure symptoms. Eligible patients must:

- Have confirmed heart failure diagnosis (NYHA Class II-IV).
- Meet specific echo criteria at screening.
- Have left ventricular ejection fraction greater than 40% documented by echo within 12 months prior to or at screening.
- Meet all other additional inclusion criteria for the study.

Participants will be randomized to receive either ziltivekimab or placebo. The study team will teach them how to inject themselves once a month and how to store the study drug. The study is expected to last for up to four years and requires participants to complete up to 20 study site visits. In addition to these visits, each participant will need to download the study app on their phone to record and share information about all their study drug injections and to fill in questionnaires.

LG Health plans to enroll 30 participants. The sponsor aims to enroll about 5,600 participants at all sites.

ACTIVE CLINICAL STUDIES AT LANCASTER GENERAL HEALTH

A complete list of active clinical studies at Penn Medicine Lancaster General Health is available online.

To access the most current list, scan the QR code below or find the link on the Resources/Links page at JLGH.org.

To make a referral to any study on the list, call the LG Health Research Institute at 717-544-1777.

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