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SPOTLIGHT ON CLINICAL RESEARCH

Cardiology and Neurology

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Editor's note: *There has been a tradition of clinical research at Lancaster General Hospital over the years, and the merger of LGH into the Penn Medicine system has added another dimension to that tradition and strengthened it. In particular, the former Lancaster General Heart and Vascular Institute organized by The Heart Group is now incorporated into the Penn Medicine Lancaster General Health Research Institute.*

JLGH is a Record of Medical Progress, and we consider it part of the JLGH mission to encourage and support the search for new medical knowledge. It therefore seemed appropriate to initiate a new section in which we draw attention to ongoing research studies at LGH. In this issue we focus on studies at the Penn Medicine Lancaster General Health Research Institute that are actively enrolling patients. This is only a partial list, and we will publish information about other studies at Penn Medicine LGH in future issues.

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.

CORONARY ARTERY DISEASE

AEGIS II

Principal Investigator: Rolf L. Andersen, M.D.

An earlier AEGIS-I study demonstrated that apolipoprotein A-I, the major functional component of high-density lipoprotein, increases cholesterol efflux in MI patients.

CSL112, a novel formulation of apoA-1, is being developed to reduce the risk of CV death, MI, and stroke in patients with Acute Coronary Syndrome (ACS). This study will evaluate its efficacy and safety.

MINT (MYOCARDIAL ISCHEMIA AND TRANSFUSION)

Principal Investigators: Jason Scott, M.D., and Todd Wood, M.D.

Clinical trials of transfusion strategies in patients with ischemic heart disease have not yielded sufficient high-quality data to guide transfusion strategies in acute MI. The persistent controversy has been cited in several major guidelines, as well as by an NIH expert panel.

This study of patients with acute MI seeks to determine whether a liberal or restrictive transfusion strategy is more effective at reducing the rate of recurrent MI or death at 30 days.

The study is sponsored by the NHLBI and Rutgers Robert Wood Johnson School of Medicine, which recently published a study of liberal vs. restrictive transfusions in cardiac surgery. Having trained in Internal Medicine at Rutgers, our own Dr. Jason Scott contacted a former mentor there about participating in this study of transfusion thresholds for patients with anemia and myocardial infarction.

This is a randomized, unblinded, two-group multicenter clinical trial. Eligible study patients are randomized to receive either the liberal or the restrictive transfusion strategy in an unblinded manner. Patients will be 30 and 180 days to ascertain outcomes. All interim medical events, such as readmissions, will be documented.

The primary aim is to determine whether a liberal transfusion strategy (Hgb 10 g/dL), compared with a restrictive transfusion strategy (Hgb 7-8 g/dL), reduces the composite 30-day outcome of all-cause mortality or nonfatal myocardial reinfarction in patients with an acute MI and Hgb < 10 g/dL.

The physicians of LGHP Hospitalists and The Heart Group will begin enrolling patients in October 2018.

HEART FAILURE ADAPTRESPONSE

Principal Investigator: Sandeep Bansal, M.D., MPH

Cardiac resynchronization therapy (CRT) by means of echo-optimized biventricular pacing reduces morbidity and mortality in patients with CHF and ventricular dyssynchrony. Medtronic developed the AdaptivCRT® algorithm to improve CRT by using preferential adaptive left ventricular pacing in certain situations rather than conventional biventricular pacing. The pre-market approval study demonstrated that the AdaptivCRT® algorithm is at least as effective as echo-optimized BiV pacing in terms of the Clinical Composite Score (CCS).

This study compares devices with the AdaptivCRT® algorithm (which can be turned on or off) with standard CRT in subjects with normal AV conduction and left bundle branch block.

NEUROLOGY

STROKE AF

Principal Investigator: Murray S. Flaster, M.D., PhD

While guidelines do recommend cardiac monitoring of patients after stroke, the optimum duration of monitoring in all patients with stroke is not known. It has generally been shown that longer durations of cardiac monitoring have better rates of detection of AF after stroke. This clinical study was designed to address known gaps in the clinical evidence related to the incidence of AF in patients with an ischemic stroke.

This study will compare the incidence of AF with Reveal LINQ (monitor arm) or standard-of-care

medical treatment (control arm) in subjects with recent stroke of presumed known origin.

HYPERLIPIDEMIA

WHOLELIFE: A WHOLE-FOOD, PLANT-BASED DIET AND ITS LIPIDEMIC EFFECTS ON PREVENTION IN A FREE-RANGE ENVIRONMENT: A PILOT STUDY

Principal Investigator: Christopher Wenger, D.O., CLS

A healthful diet incorporating abundant plant-based foods has yielded improvement in vascular disease outcomes, in part owing to lower levels of serum cholesterol. We know that consuming trans-fat, saturated fat, and dietary cholesterol raises cholesterol, while consumption of soluble fiber lowers serum cholesterol, but little is known about the effects of a whole-food, plant-based dietary eating pattern and its effects on advanced lipid testing.

This investigator-initiated, single-arm diet pilot study aims to determine the serologic effects of a whole-food, plant-based diet on primary and secondary prevention outcomes in a free-range environment. Participants will be asked to adhere to a whole-food, plant-based diet for 8 weeks. Such a diet consists of vegetables, fruits, legumes, whole grains, seeds, and nuts, while avoiding animal products such as meats, eggs, and dairy, and junk foods made with a lot of oil, sugar, and/or salt. Additionally, highly processed grains and similar foods are to be avoided. Adherence to the diet over time will be recorded.

The study will assess changes in LDL cholesterol and non-HDL cholesterol from baseline values, as well as changes in LDL particle concentration, triglyceride concentration, lipoprotein(a), and C-reactive protein.

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