Knee System Implants, Therapy to Slow Heart Failure, Breath Training

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Editor's note: This is the 11th 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. Thomas Renz (Persona Revision Knee) from Lancaster Orthopedic Group.

The Lancaster General Health Research Institute encourages readers to look to the Fall 2022 journal for more information about the exciting trauma research being conducted by Dr. Lindsey Perea and Dr. Eric Bradburn. 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

Persona Revision Knee System Study

Sponsor: Zimmer Biomet
Principal Investigator: Thomas Renz, DO

This multicenter, single-arm, retrospective study evaluates the performance, clinical benefits, and safety of Persona Revision Knee System implants. Sites enroll eligible patients who previously received one of the qualifying knee systems.

Patients are split into cohorts by the method used for the implant (e.g., Revision splined constrained condylar knee [CCK], Revision cemented posterior stabilized/constrained posterior stabilized [PS/CPS]). Study sites then monitor these patients for two years post-implant, documenting any adverse events or deviations.

The study plans to assess the improvement from baseline (implant) to two years using an objective knee scoring tool that assesses the knee joint by awarding points for pain, stability, and range of motion. Specifically, these participants will be rated using the 1989 Knee Society Clinical Rating System objective knee score (KS-KS), which is a 0-100 scale score, and the Numeric Rating Scale (NRS), which is scored on a scale of 0 to 10.

The study plans to enroll a total of 380 patients. Lancaster General Health has currently enrolled nine retrospective patients into the study. This study is being conducted by the Lancaster Orthopedic Group.

ANTHEM HFrEF: Autonomic Regulation Therapy to Enhance Myocardial Function and Reduce Progression of Heart Failure with Reduced Ejection Fraction

Sponsor: LivaNova
Principal Investigator: Roy Small, MD

The ANTHEM HFrEF trial is a multi-center, randomized, controlled trial sponsored by LivaNova. This study aims to enroll patients with New York Heart Association class II-III heart failure and reduced ejection fraction (EF ≤35%).

Participants are randomized to receive either standard guideline directed medical therapy (GDMT) or electrical vagal stimulation in addition to GDMT using the novel implanted VITARIA pacing device. The VITARIA system provides titratable, periodic stimulation of the vagal nerve to amplify parasympathetic tone. All study participants complete follow-up study visits at four weeks post-randomization, every three months for the first year, and then every four months until the study ends.

With an overall study enrollment goal of 800 participants across over 20 sites, Lancaster General Health plans to enroll at least 10 patients. While no patients have been enrolled at the time of this article, enrollment efforts continue regularly, including running study-specific reports and daily EPIC screening.

INVESTIGATOR-INITIATED STUDY

PART-HF: Parasympathetic Augmentation via Respiratory Training for Patients with Systolic Heart Failure

Grant-Funded by: Louise Von Hess Foundation
In Collaboration with: Stasis, LLC
Principal Investigator: Roy Small, MD

The primary outcome of this prospective, randomized, controlled clinical trial is to evaluate the effect of

breath training on the six-minute walk test. The study targets a population of symptomatic heart failure (NYHA Class II or III) patients with reduced Ejection Fraction (HFrEF). Participants will be randomized to one of two groups: standard guideline directed medical treatment (GDMT) (control group) or GDMT plus breath training (intervention group).

The six-minute walk test is a standard HF assessment tool used to assess aerobic and functional capacity. The walk test and additional physiologic parameters including parasympathetic tone (using heart rate variability [HRV]), quality-of-life assessment (Kansas City Cardiomyopathy Questionnaire [KCCQ]), and biomarkers will be completed at the baseline assessment, three-month assessment, and final six-month assessment.

Breath training has been shown to improve the functional capacity of heart failure patients. However, prior protocols have been too intense to allow widespread adoption. PART HF will utilize a Stasis-modified U.S. Navy SEAL respiratory training protocol to improve parasympathetic tone using diaphragmatic breathing techniques. This study aims to determine if this breath training regimen is not only beneficial to this group of heart failure patients, but also if it is easy enough to follow to promote compliance.

The participants randomized to the therapy group of the study will receive virtual breath training from a breathwork coach from Stasis. The coach will meet with participants biweekly via Zoom to promote compliance, re-educate, and answer questions. A novel "humming" practice exercise has been included, as humming has been shown to increase endogenous nitric oxide, a potent beneficial vasodilator.

Therapy arm participants will practice their breathing exercises twice a day for 15 minutes each, practice humming exercises twice a day for five minutes each, and measure their heart rate and HRV daily using a smart phone app (one minute).

Control group participants will complete clinical assessments and HRV measurements without breath training or humming exercises. At the end of their study involvement (six months), control group participants will have the option to receive the same breath training given to the therapy group participants.

The study plans to enroll 100 participants.

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