

LAPTOP

Primary Investigator:

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Sub-Investigator:

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Study Sponsor:

St. Jude Medical

Study Purpose:

The purpose of this clinical study is to evaluate the safety and clinical effectiveness of use of a physician-directed, patient self-management system, guided by left atrial pressure measurements, for use in patients with heart failure. The system allows patients to adjust their HF medications daily based on a physician-directed prescription plan and their current HF status, similar to the manner in which diabetes patients manage their insulin therapy. The goal of the LAPTOP-HF study is to demonstrate reductions in episodes of worsening heart failure (HF) and hospitalizations in patients who are managed with the left atrial pressure (LAP) management system (treatment group) versus those who receive only the current standard of care (control group).

Inclusion Criteria:

- Have ischemic or non-ischemic cardiomyopathy with either a history of reduced or preserved ejection fraction and heart failure for at least 6 months
- NYHA Class III documented at screening visit.
- Be receiving appropriate medical therapy for heart failure as per ACC/AHA guidelines (such as diuretic, angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) and beta-blocker) for at least 3 months prior to the baseline evaluation. Subject has been on stable medications maximized to the subject's tolerance of ACE or ARB and beta-blockers as determined by the study investigator for at least 30 days prior to baseline evaluation. Stable is defined as no more than a 100% increase or 50% decrease in dose. These criteria may be waived if a subject is intolerant of ACE, ARB or beta-blockers, or these agents are not indicated under the Guidelines. Such intolerance or lack of indications must be documented.
- Have a minimum of one (1) prior hospital admission within the last 12 months for acute exacerbation of HF of at least one (1) calendar date change duration requiring intravenous or invasive HF therapy. If CRT device previously implanted, the heart failure hospitalization must be ≥ 30 days after CRT implantation.
- Provide informed consent for study participation and be willing and able to comply with the required tests, treatment instructions and follow-up visits.
- Are able to schedule Therapy Initiation within two weeks. Enrollment/Randomization may be delayed until this criterion is met.

Exclusion Criteria:

- Are under the age of 18 years.
- Are pregnant.
- Have intractable HF with resting symptoms despite maximal medical therapy (persistent NYHA Class IV and ACC/AHA HF Stage D). This includes patients receiving continuous or intermittent outpatient intravenous vasoactive medications (e.g., IV inotropes, IV vasodilators), patients treated with a ventricular assist device (VAD), and patients listed for cardiac transplantation and likely to be transplanted within 12 months - even if their functional status has improved to NYHA Class III. Patients listed for cardiac transplantation who are not likely to be transplanted within 12 months and who have improved to NYHA Class III without outpatient IV vasoactive medications or a VAD are eligible for the study, if they meet the other inclusion/exclusion criteria.
- Have a resting systolic blood pressure < 80 or > 180 mmHg.
- Have an acute MI, Acute Coronary Syndrome, Percutaneous Coronary Intervention (PCI), new cardiac rhythm management device (Pacemaker, ICD, and CRT), CRM system revision, lead extraction or cardiac or other major surgery within 40 days.
- Have known coexisting, untreated, hemodynamically severe stenotic valve lesions, vegetations, hypertrophic cardiomyopathy with significant resting or provoked subaortic gradient, acute myocarditis, tamponade, or large pericardial effusion.
- Have an Atrial Septal Defect or Patent Foramen Ovale (with more than trace shunting on color Doppler or intravenous bubble study) or surgical correction of significant congenital heart disease involving atrial septum such as PFO or ASD closure device.
- Have a Stroke or Transient Ischemic Attack within 6 months.
- Have inadequate vascular access for device implantation.
- Have baseline 2-D echocardiographic evidence of, or history of, unresolved left atrial or ventricular thrombus.
- Have a recent (within 6 months) or persistent deep venous thrombosis, pulmonary or systemic thromboembolism.
- Have a life expectancy < 1 year due to another illness.
- Have coagulopathy or uninterruptible anticoagulation therapy or contraindication for all of the forms of antiplatelet/anticoagulant treatments anticipated in the protocol (See Protocol Table 6: Maintenance of Antiplatelet/Anticoagulation Options, page 39)
- Have an Estimated Glomerular Filtration Rate that remains < 30 ml/min/1.73 M2 by the MDRD method.
- Have a Liver Function Test > 3 times upper limit of normal.
- Have Severe Pulmonary Disease producing frequent hospitalizations for respiratory distress and requiring continuous home oxygen.

- Have pulmonary hypertension with a pulmonary artery systolic pressure of greater than or equal to 80 mm/Hg on screening echocardiogram.
- Have an active infection requiring systemic antibiotics.
- Have a history of active drug addiction, active alcohol abuse, or psychiatric hospital admission within the prior 2 years.
- Are currently participating in a clinical investigation that includes an active treatment arm.
- Are unable to demonstrate understanding and capability of using the PAM appropriately.
- Patient does not have access to a telephone line usable for remote PAM follow-up or electrical outlet for recharging PAM

For more information on this study, please contact the study coordinators at (989) 631-2469.