Title

Remote Patient Management After Discharge of Hospitalized Heart Failure Patients: The Better Effectiveness After Transition - Heart Failure Study

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in log-transformed NT-proBNP level. Primary analysis specified pooled comparison of the 3 highest dose vericiguat arms with placebo. Pre-specified secondary analyses included effects of individual vericiguat dose arms and testing for a vericiguat dose-response relationship. **Results:** Overall, 456 patients were randomized and 351 patients were eligible for primary end point analysis. In primary analysis, change in log-transformed NT-proBNP from baseline to week 12 was not significantly different between the pooled vericiguat group and placebo (ratio of geometric means 0.885, p=0.151). In secondary analysis, there was a dose-response relationship (p=0.017) and the 10 mg vericiguat arm showed greater reductions in log-transformed NT-proBNP than placebo at 12 weeks (ratio of geometric means 0.779, p=0.048). In the 10 mg vericiguat arm, LVEF increased at 12 weeks compared to placebo (+3.7% vs +1.5%, p=0.021). There were no significant differences in blood pressure and heart rate at 12 weeks between 10 mg vericiguat and placebo arms and adverse events were not increased. At 12 weeks, numerically fewer patients in the 5 mg (11 patients) and 10 mg vericiguat groups (10 patients) experienced cardiovascular death or HF hospitalization compared to placebo (18 patients). **Conclusions:** Although the primary analysis of the primary end point was not achieved, compared to placebo, patients receiving vericiguat 10mg daily experienced a greater reduction in NT-proBNP, greater improvement in LVEF, and fewer clinical events. As titrated in this study, vericiguat doses up to 10 mg daily were safe and did not meaningfully influence blood pressure and heart rate at 12 weeks.

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Key Words: Clinical trials, Heart failure

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Remote Patient Management After Discharge of Hospitalized Heart Failure Patients: The Better Effectiveness After Transition - Heart Failure Study

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Introduction: Heart failure is a prevalent health problem associated with costly hospital readmissions. Transitional care programs have been shown to reduce readmissions but are costly to implement. Evidence regarding the effectiveness of telemonitoring in managing the care of this chronic condition is mixed. The Better Effectiveness After Transition - Heart Failure (BEAT-HF) study is a comparative effectiveness study designed to evaluate an intervention that combines a telephonic adaptation of care transition programs with telemonitoring. **Hypothesis:** a care transition intervention that includes pre-discharge education about heart failure and post-discharge telephone nurse coaching combined with home telemonitoring of weight, blood pressure, heart rate, and symptoms will reduce all-cause 180-day hospital readmissions for older adults hospitalized with heart failure. **Methods:** 1437 individuals admitted between October 2011 and September 2013 were enrolled in a multi-center, randomized controlled trial conducted at six academic health systems in California. Patients in the intervention group received intensive patient education using the 'teach-back' method and received instruction in using telemonitoring equipment. Following hospital discharge, they received up to nine scheduled health coaching telephone calls over 6 months from nurses located in a centralized call center. The nurses also called patients and patients' physicians in response to alerts generated by the telemonitoring system, based on predetermined parameters. **Results:** This presentation will report on the study primary outcome, readmission for any cause within 180 days, and on secondary outcomes including 30-day readmission, 30-day mortality, and 180-day mortality. **Conclusions:** BEAT-HF is one of the largest randomized controlled trials of telemonitoring in patients with heart failure, and the first explicitly to adapt the care transition approach and combine it with remote telemonitoring. The study population also includes patients with a wide range of demographic and socioeconomic characteristics.

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Key Words: Heart failure, Transitions of care, Telemedicine

24294

Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure (COSMIC-HF): Final Results from a Double-blind, Randomized, Placebo-controlled, Multicenter Study

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Background: Improving myocardial contractile function remains an attractive therapeutic target in patients with heart failure and reduced ejection fraction (HFrEF). Omecamtiv mecarbil (OM) is a novel selective cardiac myosin activator which when administered intravenously increases stroke volume by prolonging LV systolic ejection time (SET) without increasing heart rate or decreasing blood pressure. COSMIC-HF (NCT 01786512) was a Phase 2 study designed to select an oral modified-release formulation and dose of OM in patients with chronic HFrEF, and to characterize its pharmacokinetics (PK) and effects on cardiac function, as well as its safety and tolerability during 20 weeks of treatment. **Methods:** COSMIC-HF was a two-phase, multicenter, randomized, double-blind, placebo-controlled trial in outpatients with a history of optimally-treated chronic HF, LVEF ≤40%, and NT-proBNP ≥200 pg/mL (≥1200 pg/mL in patients with atrial fibrillation). Two cohorts were studied during the initial dose escalation phase; Cohort 1 was randomized 1:1:1:1 to 25 mg BID of one of three OM oral formulations or placebo for 7 days. Cohort 2 was randomized in the same manner to 50 mg BID. Based on PK, safety and tolerability, one formulation was advanced into the expansion phase, where patients were randomized 1:1:1 to receive the selected OM formulation in one of two treatment groups (25 mg BID or PK-based dose escalation to 50 mg BID) or placebo for 20 weeks. PK, echocardiographic and other clinical variables were assessed. **Results:** An oral formulation of OM was selected based on data from Cohorts 1 (n=49) and 2 (n=47) of the dose escalation phase (mean age 65 years, 21% female). The expansion phase completed enrollment and follow-up of 448 patients (mean age 63 years, 17% female). For the first time, the main results of COSMIC-HF, including Cmax/Ctrough (ng/ml), SET (msec), LV end-systolic dimension (mm), and adverse events will be presented. **Conclusion:** In addition to providing information on the PK of the selected oral formulation, COSMIC-HF will furnish some data addressing the hypothesis that oral administration of OM can increase SET and provide a sustained effect on cardiac performance in patients with chronic HFrEF.

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Prevention and Rehabilitation

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The Efficacy and Safety of Varenicline, a Selective Alpha4beta2 Nicotinic Receptor Partial Agonist, for Smoking Cessation in Patients Hospitalized With Acute Coronary Syndrome: A Randomized Controlled Trial

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