PERSPECTIVE

NCT02884206

Principal Investigator: Dr. Peter Fattal, MD (S. Washington Office)

Condition: Heart Failure

Drug: LCZ696 and Placebo of Valsartan vs. Placebo of LCZ696 and Valsartan

Official Title: A Multicenter, Randomized, Double-blind, Active-controlled Study to Evaluate the Effects of LCZ696 Compared to Valsartan on Cognitive Function in Patients With Heart Failure and Preserved Ejection Fraction

Sponsor: Novartis Pharmaceuticals

Purpose: The purpose of this study is to evaluate the effect of LCZ696 compared to valsartan on cognitive function in patients with heart failure with preserved ejection fraction. Cognitive function will be assessed using a comprehensive battery of tests with an evaluation of longitudinal change of cognitive domains including memory, executive function, and attention.

Key Inclusion Criteria:

- Chronic heart failure with current symptoms NYHA class II-IV
- Left ventricular ejection fraction > 40% by echo
- Patients with at least one of the following:

Patient with heart failure hospitalization in 12 months prior to screening visit NT-proBNP > 200 pg/mL at screening

- Patient with evidence of adequate functioning to complete study assessments

Key Exclusion Criteria:

- Patients with acute decompensated heart failure requiring augmented therapy with diuretics, vasodilators and/or inotropic drugs
- Acute coronary syndrome (including myocardial infarction (MI)), cardiac surgery, other major CV surgery, or urgent percutaneous coronary intervention (PCI), carotid surgery or carotid angioplasty, history of stroke or transient ischemic attack within the 3 months prior to Screening visit or an elective PCI within 30 days prior to Screening visit
- Patients with history of hereditary or idiopathic angioedema or angioedema related to previous ACEi or ARB therapies
- Patients who require treatment with 2 or more of the following: an ACEi, an ARB or a renin inhibitor
- Patients with one of the following:
  1. Patients with serum potassium >5.2 mmol/L (mEq/L) at Screening visit
  2. Patients with serum potassium >5.4 mmol/L (mEq/L) at any visit during run-in treatment period or at randomization visit
  3. Systolic blood pressure (SBP) ≥180 mmHg at Screening visit, or
  4. SBP <110 mmHg at Screening visit, or
  5. SBP <100 mmHg or symptomatic hypotension as determined by the investigator at Visit 103 or at randomization visit
  6. Body mass index (BMI) >40 kg/m^2
- Patients with:
  1. known pericardial constriction, genetic hypertrophic cardiomyopathy, infiltrative cardiomyopathy or
  2. history of any dilated cardiomyopathy, including peripartum cardiomyopathy, chemotherapy induced cardiomyopathy, or viral myocarditis
- Life-threatening or uncontrolled dysrhythmia, including symptomatic or sustained ventricular tachycardia and atrial fibrillation or flutter with a resting ventricular rate >110 beats per minute

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Key Exclusion Criteria (Continued):

- Inability to perform cognitive battery or other study evaluations based on significant motor (e.g. hemiplegia, muscular-skeletal injury) or sensory (blindness, decreased or uncorrected visual or auditory acuity) skill
- According to the MRI central reader, MRI evidence of:
  1. >2 lacunar infarcts or large cortical or subcortical infarct > 1cm^3
  2. any white matter lesion that corresponds to an overall Fazekas score of 3 that requires at least 1 confluent hyperintense lesion on the FLAIR sequence, which is ≥20 mm in any dimension
  3. Clinically significant cerebral pathology for example large cerebral aneurysm or space occupying lesion
  4. ≥4 micro hemorrhages as seen on gradient echo image
- Mini mental state examination score less than 24 at screening

Source: https://clinicaltrials.gov/ct2/show/NCT02884206
Retrieved on: 7/7/2017