SHORT TITLE: EMPEROR-Preserved

RESEARCH PROTOCOL TITLE: A phase III randomized, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF).

PRINCIPAL INVESTIGATOR: David Lewis, MD

RESEARCH SPONSOR: Boehringer Ingelheim

Clinical Trials.Gov Listing at:
https://clinicaltrials.gov/ct2/show/NCT03057951?term=empagliflozin&rank=50

STUDY PURPOSE
This study examines how safe and well the study drug empagliflozin works in treating subjects who have a type of long-term heart failure that includes preserved Ejection Fraction. The study compares subjects who take the study drug to subjects who take a placebo (a "dummy treatment" which looks like empagliflozin but contains no active ingredients).

STUDY PROCEDURES
The study will last 20-38 months, maybe longer or shorter, with study visits every 6 months after the first year. Phone call visits will be conducted in between clinic visits. There are more frequent visits the first year of the study. During the study visits vital signs (weight, blood pressure and pulse) will be taken, questionnaires completed, and study medication will be collected and re-dispensed. Some visits will include a physical exam by a study doctor.

ELIGIBILITY CRITERIA FOR SUBJECTS
20 years of age or older
Be willing to give informed consent
Must have chronic heart failure for at least 3 months
Be willing to comply with the study requirements

SUBJECT PAYMENT
Participants will be compensated $50 (fifty) for each completed clinic study visit.

RESEARCH LOCATION AND CONTACT PERSON
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