Control Number:	23-LBCT-20868-ACC
Session Number:	**411**
Session Title:	**Featured Clinical Research III**
Location:	La Nouvelle B
Session Time:	Monday, March 6, 2023, 12:45 pm - 2:00 pm
Presentation Number:	411-14
AnalysisComplete:	No
AnalysisCompleteDate:	12/01/22
EnrollmentCompleted:	Yes
EnrollmentCompleteDate:	
EnrollmentStart:	02/24/21
IndustrySponsor:	This is an investigator-initiated trial sponsored by AstraZeneca.
OtherTrialType:	
PublishedAcronym:	CAMEO-DAPA
PublishedNameofTrail:	Evaluation of the Cardiac and Metabolic Effects of Dapagliflozin in Heart Failure With Preserved EF
TrialDataCenter:	Mayo Clinic
TrialFinding:	We remain blinded as last patient visit is 11/9. 36 patients have completed the study, with assessments of invasive hemodynamics at rest and with exercise, cardiac function by stress echocardiography, and blood/plasma volume.
TrialInstitution:	Mayo Clinic
TrialSponsor:	Rickey Carter
TrialSummary:	This is a mechanistic clinical trial designed to enhance understanding of the mechanisms leading to clinical benefit from the SGLT2 inhibitor dapagliflozin in HFpEF. Effects on cardiac function, hemodynamics, and volume will be assessed.
TrialType:	Smaller study/randomized clinical trial (RCT)
TrialTypeDevice:	
TrialTypeDoubleBlind:	True
TrialTypeDrug:	True
TrialTypeOther:	
TrialTypePlacebo:	True
TrialTypeRandomized:	True
TrialTypeStrategy:	
Publishing Title:	Evaluation Of The Mechanism Of Benefit For Dapagliflozin In Heart Failure With Preserved Ejection Fraction: An Invasive Hemodynamic Randomized Trial
Author Block:	Barry Borlaug, Yogesh N V Reddy, Amanda Braun, Hidemi Sorimachi, Massar Omar, Rickey E. Carter, Michael Jensen, Mayo Clinic, Rochester, MN, USA
Abstract Body:	**Background:** Sodium-glucose co-transporter 2 inhibitors (SGLT2i) have been shown to reduce adverse outcomes and improve health status in patients with heart failure and preserved ejection fraction (HFpEF), but to date, the mechanisms responsible for these benefits remain unclear. Proposed mechanisms include salutary effects on hemodynamics, cardiac function and reserve, and volume expansion, but prospective studies directly assessing these measures employing the rigor of a randomized clinical trial are lacking. **Methods:** This is a randomized, double-blind placebo-controlled trial testing the effects of the SGLT2i dapagliflozin 10 mg once daily in patients with HFpEF. The primary endpoint is change in pulmonary capillary wedge pressure incorporating rest and exercise values before and after 24 weeks of treatment using a mixed effects model. Key secondary endpoints include measures of cardiac function at rest and with exercise, myocardial metabolism through transcardiac blood sampling (arterial and coronary sinus cannulation), and plasma volume. Participants underwent end point assessment at baseline and after 24 weeks treatment with dapagliflozin or placebo using invasive cardiopulmonary exercise testing with high fidelity micromanometer right heart catheterization, transcardiac blood sampling at rest/exercise and plasma volume assessment.

Results: The goal sample size of 36 patients was enrolled, allowing for 93% power to detect a 20% or greater reduction in pulmonary capillary wedge pressure. 38 patients were randomized of whom 36 completed all study visits; 1 patient withdrew, and 1 patient is scheduled for final study visits on 11/9/22. We expect to complete analysis and database lock in November and unblind for final analyses in December 2022 to allow presentation of final results in early 2023.
Conclusion: SGLT2i have been unequivocally shown to improve clinical status in HFpEF, but the mechanisms remain unclear. This mechanistic trial, which may represent the last placebo-controlled trial of this therapy in HFpEF, is positioned to provide novel, gold standard invasive data on the hemodynamic, metabolic, and cardiac functional effects of dapagliflozin in HFpEF.