

FOR IMMEDIATE RELEASE

**CORTAHF study - Burst steroid therapy for acute heart failure: a randomized, pilot trial met its primary and both secondary endpoints**

DURHAM, NC, Sept. 28, 2022 -- Heart Initiative, the sponsor of the CORTAHF (Effect of Short-Term Prednisone Therapy on C-reactive Protein Change in Emergency Department Patients With Acute Heart Failure and Elevated Inflammatory Markers) study, announced today the results of the main study analysis.

CORTAHF assessed whether burst steroid therapy reduces inflammation and results in better quality of life and clinical outcomes in AHF. In this study 100 patients with AHF, NT->1500 pg/mL, and high-sensitivity C-reactive protein (hsCRP)>20 mg/L were randomized 1:1 to oral, once daily 40 mg prednisone for 7 days or usual care, without blinding. Patients were followed for 90 days. At day 7 the primary endpoint, hsCRP decreased in both arms – adjusted geometric mean ratios (GMRs) were 0.30 and 0.40 in the prednisone and usual care arms (ratio of GMRs 0.75, 95% CI 0.56-1.00, p=0.0498). The 90-day risk of worsening HF, HF readmission or death was significantly lower in the prednisone group (10.4%) than in usual care (30.8%) (hazard ratio 0.31, 95% CI 0.11-0.86, p=0.016). The EQ-5D visual analog scale score increased more in the prednisone group on day 7 (LS mean difference 2.57, 95% CI 0.12-5.01 points, p=0.040). All effects were statistically significant in the prespecified subgroup with centrally-measured IL-6>13 pg/mL, which was blinded to both investigators and patients. Adverse events, particularly hyperglycemia, occurred more in the prednisone group with no difference in infection rate.

The results of the study suggest that in patients with AHF, burst steroid therapy may be associated with reduced inflammation, improved quality of life at day 7 and reduced 90-day risk of death or worsening HF. Large prospective studies are needed to evaluate these findings.

The full CORTAHF trial results will be presented at the upcoming meeting of the European society of Cardiology, Dec 20<sup>th</sup> 2024 at 9:33 AM London time and published in the Eur J Heart Failure simultaneously - <https://onlinelibrary.wiley.com/doi/10.1002/ejhf.3452>

**About Heart Initiative**

The Heart Initiative is a non-profit organization created in 2009 whose mission is, through research, to increase public awareness and knowledge of cardiovascular diseases particularly heart failure, and to improve the early diagnosis and treatment of cardiovascular diseases through increasing usage of proven therapies and improving adherence. It sponsored multiple studies in Heart failure examining effects of common generic medications such as Thesus – a registry of HF in sub-Saharan Africa, BEAHEFT that examined the effects of Hydralazine/nitrates in HF in Africa, STRONG HF that examined early rapid uptitration of GDMT after an AHF admission and led to a change in guidelines for the treatment of HF and other studies. For more details - <https://www.worldheartinitiative.org>