

# GUIDE-HF: Hemodynamic-guided management of heart failure – randomized arm primary outcomes

**Purpose:** To evaluate whether pulmonary artery (PA) pressure-guided heart failure management leads to a clinical benefit in a broad range of heart failure patients (NYHA Class II, III, or IV), with either a recent hospitalization for heart failure or elevated natriuretic peptides.

**Trial Design:** Single blind, randomized controlled trial of PA pressure-guided therapy in NYHA class II-IV pts. (N=1000) with either HF hospitalization or elevated natriuretic peptide. Pts. received an implantable PA pressure sensor (CardioMEMS HF System) followed by randomization to either treatment group with provider remote access, or control group without provider access. Median follow-up 11.7 months.

**Primary Endpoints:** Composite of all-cause mortality and total heart failure events ( heart failure hospitalizations and urgent heart failure hospital visits) at 12 months. The pre-COVID impact analysis included all primary endpoints up to March 13, 2020.

	Remote Hemodynamic Guided Care (n=497)	Standard Care ( no access to PA pressures) (n=503)	HR (95%CI)	P value
<b>Overall primary endpoint analysis</b>	253	289	0.88 (0.74-1.05)	0.16
Components of overall primary endpoint				
HF events	213	252	0.85 (0.70-1.03)	0.096
Urgent HF hospital visits	28	27	1.04 (0.61-1.77)	0.89
HF hospitalizations	185	225	0.83 (0.68-1.01)	0.064
Death	40	37	1.09 (0.70-1.70)	0.71
<b>Pre-COVID impact analysis-primary endpoint</b>	177	224	0.81 (0.66-1.00)	0.049
Components of Pre-COVID impact analysis				
HF events	147	199	0.76(0.61-0.95)	0.014
Urgent HF hospital visits	23	23	1.02(0.57-1.82)	0.95
HF hospitalizations	124	176	0.72(0.57-0.92)	0.0072
Death	30	25	1.24(0.73-2.11)	0.42
<b>Results:</b>				
Hemodynamic-guided management across the spectrum of ejection fraction and symptom severity was safe but did not reduce a composite of mortality and heart failure events.				
COVID-19 pandemic impacted the outcomes of the trial. The pre-COVID impact analysis indicated a benefit of hemodynamic-guided management on the primary outcome in the pre-COVID-19 period, primarily driven by a lower HF hospitalization rate (28%) compared to control group				

Results reflect the data available at the time of presentation.

