The Targeting Acute Congestion with Tolvaptan In Congestive Heart Failure Study TACTICS-HF

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Background

- Congestion is the primary driver of symptoms in acute heart failure (AHF)
- Available strategies for decongestion in AHF are associated with significant limitations
- Short-term data from the EVEREST trial of the vasopressin antagonist Tolvaptan suggested clinically important effects on signs and symptoms of congestion
- Tolvaptan improved dyspnea at Day 1 in the study
- The effects of Tolvaptan on dyspnea relief were greatest within 12 h after the initial dose, and persisted up to 20 hours compared to placebo (Figure)
- Tolvaptan may be a useful adjunct to treating congestion in patients with AHF

Primary Aim and Hypothesis

- To compare the effects of oral Tolvaptan vs. placebo as an adjunct to fixed dose IV furosemide on dyspnea relief in patients with AHF
- The addition of oral Tolvaptan to fixed dose furosemide will be more effective at relieving dyspnea than fixed dose furosemide alone

Study Design

- 250 patient, randomized, double blind, placebo controlled trial

Primary Endpoint

- AHF (Dyspnea, Elevated BNP, Signs/symptoms) <24 hr after presentation
- Fixed Dose Furosemide + Tolvaptan
- Dosing at 0, 24 and 48 hr
- Fixed Dose Furosemide + Placebo
- % with at least moderate improvement in dyspnea by Likert scale at both 8 AND 24 hours AND without the need for rescue therapy or death within 24 hours

Secondary Endpoints

- Changes in renal function, body weight and fluid loss
- Change in dyspnea
- Proportion with worsening or persistent HF
- Length of stay
- Total days hospitalized or deceased
- Death, re-hospitalization, or urgent clinic visit

Current Trial Sites

- Hennepin County Medical Center
- Vanderbilt University Medical Center
- Emory University School of Medicine
- Duke University Hospital
- Mid Carolina Cardiology Research
- Montefiore Medical Center
- Allegheny Valley Hospital
- University of North Carolina Hospital
- The Christ Hospital
- Grand View - Lehigh Health Valley Services
- University of Colorado at Denver and Health Sciences Center
- Mercer University School of Medicine
- Lancaster Heart Foundation
- University of Cincinnati

References


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Figure. Improvement in dyspnea with Tolvaptan compared to placebo in EVEREST (Pang PS et al. Eur Heart J. 2009).