The LION-HEART study was a multicentre, double-blind, randomised, parallel-group, placebo-controlled trial evaluating the efficacy and safety of intravenous administration of intermittent doses of levosimendan in outpatients with advanced chronic heart failure" Comín-Colet et al (2018).

Abstract:

AIMS: The LION-HEART study was a multicentre, double-blind, randomised, parallel-group, placebo-controlled trial evaluating the efficacy and safety of intravenous administration of intermittent doses of levosimendan in outpatients with advanced chronic heart failure.

METHODS AND RESULTS: Sixty-nine patients from 12 centres were randomly assigned at a 2:1 ratio to levosimendan or placebo groups, receiving treatment by a 6-hour intravenous infusion (0.2 µg/kg/min without bolus) every 2 weeks for 12 weeks. The primary endpoint was the effect on serum concentrations of N-terminal pro-B-type natriuretic peptide (NT-proBNP) throughout the treatment period in comparison with placebo. Secondary endpoints included evaluation of safety, clinical events and health-related quality of life (HRQoL). The area under the curve (AUC, pg.day/mL) of the levels of NT-proBNP over time for patients who received levosimendan was significantly lower than for the placebo group (344 × 103 [95% Confidence Interval (CI) 283 × 103 -404 × 103] vs. 535 × 103 [443 × 103 -626 × 103], p = 0.003). In comparison with the placebo group, the patients on levosimendan experienced a

reduction in the rate of heart failure hospitalisation (hazard ratio 0.25; 95% CI 0.11-0.56; P = 0.001). Patients on levosimendan were less likely to experience a clinically significant decline in HRQoL over time (P = 0.022). Adverse event rates were similar in the two treatment groups.

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CONCLUSIONS: In this small pilot study, intermittent administration of levosimendan to ambulatory patients with advanced systolic heart failure reduced plasma concentrations of NT-proBNP, worsening of HRQoL and hospitalisation for heart failure. The efficacy and safety of this intervention should be confirmed in larger trials.

Reference:

Comín-Colet, J., Manito, N., Segovia-Cubero, J., Delgado, J., García Pinilla, J.M., Almenar, L., Crespo-Leiro, M.G., Sionis, A., Blasco, T., Pascual-Figal, D., Gonzalez-Vilchez, F., Lambert-Rodríguez, J.L., Grau, M. and Bruguera, J. (2018) Efficacy and safety of intermittent intravenous outpatient administration of levosimendan in patients with advanced heart failure: the LION-HEART multicentre randomised trial. European Journal of Heart Failure. February 6th.

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