Effect of 1, 25-Dihydroxyvitamin D3 (calcitriol) on Mortality of Hospital Acquired Sepsis/Septic Shock: A Randomized, Double-blind, Placebo-controlled Study (Interim Analysis)

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Background: Sepsis and septic shock are common in critically ill patients and associated with high mortality. Studies demonstrate an association between vitamin D deficiency and poor outcomes including long hospital stay and mortality.

Objective: To investigate the effect of 1, 25-dihydroxyvitamin D3 (calcitriol) administration in patients with hospital acquired sepsis/septic shock on mortality.

Methods: A randomized double-blind, placebo-controlled, single center trial, conducted from November 2016 through December 2017 at Siriraj Hospital. Patients with hospital acquired sepsis or septic shock were randomized to receive either a single dose of calcitriol 2 micrograms or placebo intravenously within 12 hours after diagnosis. The primary outcome was 28-day mortality after drug administration. Secondary outcomes were hospital mortality, hospital length of stay, SOFA-CV score improvement, and new requirement for ventilator, renal and vasopressor support.

Results: A total of 24 patients were included in the analysis (12 in the calcitriol group and 12 in the placebo group). Mortalities, both at 28 days and at discharge were not different. The additional requirements for ventilator, renal, and vasopressor support were similar. Also, hospital length of stay and SOFA-CV score improvements were the same. In patients with vitamin D deficiency (n=15), calcitriol administration did not change 28-day mortality and hospital mortality. New requirement for vasopressor support was lower in calcitriol group. In addition, other outcomes remained unchanged.

Conclusion: In this interim analysis, the administration of calcitriol at the dose of 2 micrograms in patients with hospital acquired sepsis/septic shock cannot reduce 28-day mortality and hospital mortality. Also, it does not alter hospital length of stay and new need for organ support. The study is in process to include more patients as planned.

Keywords: 1, 25-dihydroxyvitamin D3, Calcitriol, Hospital acquired sepsis, Septic shock