

## A Randomized, Controlled Trial of *Panax quinquefolius* Extract (CVT-E002) to Reduce Respiratory Infection in Patients With Chronic Lymphocytic Leukemia.

[High KP](#), [Case D](#), [Hurd D](#), [Powell B](#), [Lesser G](#), [Falsey AR](#), [Siegel R](#), [Metzner-Sadurski J](#), [Krauss JC](#), [Chinnasami B](#), [Sanders G](#), [Rousey S](#), [Shaw EG](#).

**Source** Sections of Infectious Diseases, Winston-Salem, North Carolina; Department of Hematology and Oncology, Winston-Salem, North Carolina.

### Abstract

**BACKGROUND:** Chronic lymphocytic leukemia (CLL) patients are at high risk for acute respiratory illness (ARI).

**OBJECTIVE:** We evaluated the safety and efficacy of a proprietary extract of *Panax quinquefolius*, CVT-E002, in reducing ARI.

**METHODS:** This was a double-blind, placebo-controlled, randomized trial of 293 subjects with early-stage, untreated CLL conducted January-March 2009.

**RESULTS:** ARI was common, occurring on about 10% of days during the study period. There were no significant differences of the 2 a priori primary end points: ARI days ( $8.5 \pm 17.2$  for CVT-E002 vs  $6.8 \pm 13.3$  for placebo) and severe ARI days ( $2.9 \pm 9.5$  for CVT-E002 vs  $2.6 \pm 9.8$  for placebo). However, 51% of CVT-E002 vs 56% of placebo recipients experienced at least 1 ARI (difference, -5%; 95% confidence interval [CI], -16% to 7%); more intense ARI occurred in 32% of CVT-E002 vs 39% of placebo recipients (difference, -7%; 95% CI, -18% to 4%), and symptom-specific evaluation showed reduced moderate to severe sore throat ( $P = .004$ ) and a lower rate of grade  $\geq 3$  toxicities ( $P = .02$ ) in CVT-E002 recipients. Greater seroconversion (4-fold increases in antibody titer) vs 9 common viral pathogens was documented in CVT-E002 recipients (16% vs 7%,  $P = .04$ ).

**LIMITATIONS:** Serologic evaluation of antibody titers was not tied to a specific illness, but covered the entire study period.

**CONCLUSION:** CVT-E002 was well tolerated. It did not reduce the number of ARI days or antibiotic use; however, there was a trend toward reduced rates of moderate to severe ARI and significantly less sore throat, suggesting that the increased rate of seroconversion most likely reflects CVT-E002-enhanced antibody responses.

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