A phase III randomized, double-blind, placebo controlled trial of North American (NA) ginseng (Panax quinquefolium) extract (CVT-E002) in patients with chronic lymphocytic leukemia: Effect on respiratory infection and antibiotic use.

Meeting:
2010 ASCO Annual Meeting
Session Type and Session Title:
General Poster Session, Leukemia, Myelodysplasia, and Transplantation
Abstract No:
6578
Citation:
J Clin Oncol 28:15s, 2010 (suppl; abstr 6578)
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Abstract:

Background: Chronic lymphocytic leukemia (CLL) is the most common adult leukemia and patients are at high risk for respiratory infection. **Methods:** We investigated the safety and efficacy of an extract of NA ginseng, CVT-E002 (200 mg po bid) to reduce acute respiratory illness (ARI) in CLL patients during Jan-Mar, 2009 in a randomized, placebo-controlled trial. 293 subjects with untreated CLL were enrolled through the Community Clinical Oncology Programs affiliated with Wake Forest University Cancer Center's Research Base as well as NCI Cancer Trials Study Unit sites. ARI symptoms were recorded in daily diaries and rated (0 = absent; 1 = mild, 2 = moderate, 3 = severe). **Results:** Median subject age was 66 (range 43-87), 57% were male, and 77% of subjects had received influenza vaccine. Medication compliance was > 97% for both CVT-E002 and placebo. CVT-E002 was well tolerated with no difference in adverse events between groups. 50% of CVT-E002 recipients experienced ≥ 1 ARI day vs. 55% of placebo recipients (absolute diff -5%, 95% C.I. -16%,7%). 27% of CVT-E002 recipients experienced ≥ 1 severe ARI day (ARI + fever and/or limited activity) vs. 30% of placebo recipients (absolute diff -3%, 95% C.I. -14%,7%). When only mod-severe symptoms were considered, ARI occurred in 31% of CVT-E002 recipients vs. 39% in the placebo group (absolute diff -8%, 95% C.I. -19%,3%) There was no difference in mean ARI days (8.2 ± 16.8 in

CVT-E002 recipients vs. 6.8 ± 13.3 in placebo) or antibiotic use. Examination of secondary endpoints (e.g. serologically confirmed viral infections, immunologic parameters) is ongoing. **Conclusions:** CVT-E002 did not reduce the mean number of ARI days, although there was a trend toward a lower incidence of ARI and mod-severe ARI. CVT-E002 was well tolerated.
Supported by Afexa Life Sciences and NIH/NCI/DCP grant 3 U10 CA 81851.