AE-941, a standardized shark cartilage, does not improve lung cancer survival

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The anti-cancer drug AE-941, a shark cartilage derivative, did not improve overall survival in patients with inoperable stage III non-small cell lung cancer, according to a study published online May 26 in the *Journal of the National Cancer Institute.*

The study was one of the few phase III trials of a shark cartilage-derived pharmaceutical agent. Shark cartilage is known to have properties that are antiangiogenic, which means it is able to prevent the growth of new blood vessels around tumors. Antiangiogenic therapies have been shown to improve survival in non-small cell lung and other cancer patients.

To determine whether the addition of AE-941 to standard chemoradiotherapy in treating patients with non-small cell lung cancer improves overall survival, Charles Lu, M.D., from The University of Texas MD Anderson Cancer Center, and colleagues, conducted a randomized, double-blinded, placebo-controlled phase III clinical trial in community and academic oncology centers in the United States and Canada. The coordinating center was the Community Clinical Oncology Program Research Base at MD Anderson.

The study enrolled 379 patients with unresectable non-small cell lung cancer between May 2000 and February 2006. The patients were treated with chemoradiotherapy and either AE-941 or a placebo, given during and after chemoradiotherapy. The trial was closed early due to low accrual.

The researchers found no statistically significant differences in overall survival, progression-free survival, time to progression, and tumor response rates between the AE-941 and placebo arms of the study. The placebo arm had a median overall survival of 15.6 months, whereas the AE-941 arm had a median survival of 14.4 months. The placebo arm had a median time to progression of 10.7 months, compared to 11.3 months for the AE-941 arm. There was also no difference in progression-free survival between the two arms. AE-941 was well-tolerated.

The authors conclude that "The addition of AE-941 to chemoradiotherapy did not improve overall survival in patients with unresectable stage III NSCLC. This study does not support the use of shark cartilage-derived products as a therapy for lung cancer."

The authors also note the impetus for the trial comes from "the widespread use of poorly regulated complementary and alternative medicine products, such as shark cartilage-derived agents, among patients with advanced cancer, a population likely to be vulnerable to unsubstantiated marketing claims."

In an accompanying editorial, Jeffrey White, M.D., of the Division of Cancer Treatment and Diagnosis, the National Cancer Institute, said that although the study does not provide much promise for the usage of shark cartilage extracts, there is growing interest in how purified shark cartilage might be used in therapeutics.

Furthermore, this study showed that "the slight but statistically significant decrease in grade 3 toxicities noted in the AE-941 treated group in the current study may be a sign of activity that is worthy of further investigation," the editorialist writes.

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