

Phase II trial of ipilimumab-nivolumab combo shows promise in advanced melanoma

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Giving the two immunotherapies ipilimumab and nivolumab simultaneously yielded better treatment responses than ipilimumab alone in patients with advanced melanoma who received no prior treatment, according to phase II clinical trial data presented here at the AACR Annual Meeting 2015, April 18-22. This study is being simultaneously published in the *New England Journal of Medicine*.

"Preclinical studies in animal models demonstrated that a combination of anti-CTLA-4 and anti-PD-1 had better outcomes than when the two drugs were given individually in sequence. In a phase I trial testing the combination of [ipilimumab](#) and nivolumab for safety, some early positive responses were seen. So we tested this combination in a blinded fashion in this phase II trial," said F. Stephen Hodi, MD, director of the Melanoma Center at Dana-Farber Cancer Institute, and associate professor of medicine at Harvard Medical School in Boston.

In this phase II, double-blind trial, 142 patients with advanced melanoma who had not received prior therapy were enrolled. Of these patients, 109 had the normal form of the gene BRAF in their tumors and 33 had BRAF V600 mutations. Patients were randomly assigned (2:1) to receive ipilimumab plus nivolumab followed by nivolumab alone (95 patients) or ipilimumab plus placebo followed by placebo alone (47 patients).

Among the patients without BRAF mutations, those who received ipilimumab plus nivolumab had an overall response rate of 60 percent, which included 17 percent and 43 percent complete and partial response

rates, respectively; those who received ipilimumab plus placebo had an overall response rate of 11 percent, with no complete responses and 11 percent partial response rate.

Among the patients with BRAF V600 mutations, those who received the drug combination had an overall response rate of 44 percent, which included 17 percent and 26 percent complete and partial response rates, respectively.

"Side effects for patients from the combination arm were higher compared with patients treated with ipilimumab alone, and this needs to be interpreted with caution," Hodi said. "Following up with [patients](#) in the current study over a longer period of time is an important step."

Provided by American Association for Cancer Research

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