

Budesonide is not beneficial for the treatment of diarrhea in metastatic melanoma patients

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Patients with stage III or IV melanoma taking ipilimumab and the oral steroid budesonide to reduce side effects did not have less diarrhea, a known side effect of ipilimumab, according to results of a phase II trial published in *Clinical Cancer Research*, a journal of the American Association for Cancer Research.

These findings would "discourage the prophylactic use of budesonide to reduce the gastrointestinal [side effects](#) of ipilimumab," said researcher Jeffrey Weber, M.D., Ph.D. Weber is a senior member at the Moffitt Cancer Center and director of the Donald A. Adam Comprehensive [Melanoma](#) Research Center, Tampa, Fla.

Weber and colleagues gave 10 mg/kg of ipilimumab to 115 patients every three weeks, for four doses. This was combined with daily budesonide for one group and [placebo](#) control for another.

After four months of treatment, they found that budesonide did not affect the rate of diarrhea - it occurred in 32.7 percent of patients treated with the drug and 35 percent of those who received placebo, according to the study. Median overall survival was 17.7 months among those treated with budesonide compared with 19.3 months among those who received placebo.

Additionally, the researchers saw anti-tumor responses in 10 to 15

percent of patients, without an apparent difference between patients treated with budesonide and those who received placebo.

"This study attempted to decrease the side effects of ipilimumab by using a preventative enteric steroid regimen. This approach failed to accomplish that goal," said Jennifer Grandis, M.D., who is an editorial board member for Clinical Cancer Research. She is professor of [otolaryngology](#) and pharmacology at the University of Pittsburgh School of Medicine, and co-leader of the Head and Neck Cancer Program at the University of Pittsburgh Cancer Institute.

"The conclusion that the therapy is active in melanoma is justified, but not particularly novel. The study supports the contention that ipilimumab has use as a treatment in this disease, but more research is needed to elaborate on these findings and unveil ways to manage and potentially reduce side effects associated with this drug's use," she said.

Weber said he was not surprised by the favorable clinical results of this study and agreed that ipilimumab should be pursued in further clinical trials.

"Ipilimumab appears to result in prolonged median and overall survivals in patients with stage IV melanoma," he said. "A significant proportion of patients receiving ipilimumab may have long-term survival."

Ipilimumab (also known as MDX-010 or MDX-101) is in a class of drugs called monoclonal antibodies, which stimulate the body's own immune system to fight disease. It is currently in clinical trials for the treatment of melanoma. Budesonide is currently used for the treatment of inflammatory bowel disease, asthma, non-infectious rhinitis and for the treatment and prevention of growths in the nasal cavity.

Source: American Association for [Cancer](#) Research ([news](#) : [web](#))

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