

Clinical trial generates promising results for immunotherapy drug nivolumab in patients with advanced skin cancer

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Numerous studies have shown that drugs called immune checkpoint inhibitors can boost the immune system's response against various cancers. Now a phase II clinical trial has demonstrated that patients with a serious form of skin cancer called advanced cutaneous squamous cell

carcinoma can benefit from the immune checkpoint inhibitor nivolumab. The research is published by Wiley online in *Cancer*, a peer-reviewed journal of the American Cancer Society.

Two other [immune checkpoint inhibitors](#)—cemiplimab and pembrolizumab—have been approved by the US Food and Drug Administration for the treatment of advanced cutaneous squamous cell carcinoma in recent years. This new study is the first to report clinical trial results for nivolumab.

The single-arm trial included 24 patients who received nivolumab at 3 mg/kg every two weeks until they experienced [cancer](#) progression, developed unacceptable toxicity, or had received 12 months of treatment.

During the trial, 14 patients (58.3%) benefited from the treatment, with their cancers demonstrating a response. Treatment-related adverse events of any grade and grade ≥ 3 occurred in 21 (87.5%) and six [patients](#) (25%), respectively, and one patient discontinued nivolumab due to toxicities. Prior exposure to radiotherapy was associated with a worse response.

"This is the first study to investigate nivolumab in this patient population, and it provides further evidence supporting the use of immune checkpoint blockers as standard therapies in cutaneous squamous cell carcinoma," said lead author Rodrigo R. Munhoz, MD, of the Hospital Sírío-Libanês, in Brazil.

An accompanying editorial notes that although the trial was small, its results were similar to those reported with pembrolizumab and cemiplimab. "In addition to providing more assurance to the clinical activity of different [immune checkpoint] inhibitors in this disease, this replicated data may permit a more widespread utilization of these agents

in managing a common disease with global implications," the authors wrote.

More information: A phase 2 study of first-line nivolumab in patients with locally advanced or metastatic cutaneous squamous-cell carcinoma, *Cancer* (2022). [DOI: 10.1002/cncr.34463](https://doi.org/10.1002/cncr.34463)

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