

Immunotherapy drug used as first-line therapy for Merkel cell carcinoma improved survival

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Adam Riker, MD, FACS, Professor of Surgery and Chief, Section of Surgical Oncology at LSU Health New Orleans School of Medicine Credit: LSU Health New Orleans

A multi-center phase II clinical trial investigating pembrolizumab as a first-line and programmed cell death-1 therapy in patients with advanced



Merkel cell carcinoma reports lasting tumor control, generally manageable side effects and improved overall survival. The results are published online in the *Journal of Clinical Oncology*.

LSU Health New Orleans' Adam Riker, MD, FACS, Professor and Chief of Surgical Oncology, led the study at its School of Medicine and Stanley S. Scott Cancer Center.

"This study shows the amazing ability of our immune system to fight off and destroy an aggressive form of skin cancer called Merkel cell carcinoma," says Dr. Riker. "The study drug, pembrolizumab, which is a new form of immunotherapy, blocks a specific receptor in our bodies, resulting in a super charging of our immune system to both recognize and destroy cancer cells. The overall impressive results show that this form of immunotherapy is quite effective, giving us an important treatment option for patients with Merkel Cell Carcinoma that has spread within the body."

Fifty patients, aged 46—91 years, were enrolled in the open-label, nonrandomized study. Patients were given pembrolizumab intravenously every three weeks for up to two years. Fifty-six percent of participants responded to the drug—24% had a complete response, and 32%, a partial response. The average length of progression-free survival was 26.8 months, with a 24-month rate of 48.3%. The overall survival rate at 24 months was 68.7%.

Nearly all of the participants (96%) experienced some type of treatment-related side effect, and seven patients discontinued the trial because of them. The authors note that one death occurred in a 73-year-old patient with widely metastatic Merkel cell carcinoma and pre-existing atrial fibrillation who withdrew from the trial and died 10 days after a single infusion of pembrolizumab.



According to the National Cancer Institute, Merkel cell carcinoma is a disease in which malignant (cancer) cells form in the skin. Sun exposure and a weak immune system can affect the risk of Merkel cell carcinoma. Though rare, the incidence of Merkel cell carcinoma increased by 95% between 2000 and 2013. The five-year overall survival rate ranges between 14 and 27% for advanced disease.

The first drug approved to treat metastatic Merkel cell carcinoma, avelumab, did not gain FDA approval until 2017. The authors add, in 2016, guidelines listed chemotherapy as the sole treatment option for advanced Merkel cell carcinoma. In 2017, pembrolizumab was recommended after chemotherapy; and in 2018, avelumab, nivolumab, and pembrolizumab were all recommended as preferred first-line therapies, ahead of chemotherapy.

The fact that the incidence is highest in people who are immunosuppressed provides some support for the idea that Merkel cell carcinoma is an immunogenic cancer, one that is related to immune function, and a good candidate for immunotherapy. The National Cancer Institute defines immunotherapy as "a type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases. Some types of immunotherapy only target certain cells of the immune system. Others affect the immune system in a general way. Types of immunotherapy include cytokines, vaccines, bacillus Calmette-Guerin (BCG), and some monoclonal antibodies." Pembrolizumab is a monoclonal antibody.

More information: Paul Nghiem et al, Durable Tumor Regression and Overall Survival in Patients With Advanced Merkel Cell Carcinoma Receiving Pembrolizumab as First-Line Therapy, *Journal of Clinical Oncology* (2019). DOI: 10.1200/JCO.18.01896



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