Brain tumor vaccine trial shows promising results

April 16 2007

A vaccine for treating a recurrent cancer of the central nervous system that occurs primarily in the brain has shown promise in preliminary data from a clinical trial at the University of California, San Francisco.

Known as a glioma, this cancerous tumor is always fatal. Findings from a group of 12 study patients showed that vitespen vaccination (trademarked as Oncophage) was effective in stimulating the patient's immune system to attack the tumor cells, a function that is known medically as tumor-specific immune response. All the patients had recurrent, high-grade glioma, and all showed the immune response. The vaccine is made from the patient's own tumor.

The clinical trial was conducted by the UCSF Brain Tumor Research Center. Results were presented today (April 16) at the 75th annual meeting of the American Association of Neurological Surgeons in Washington, DC.

"In this trial, we have observed a correlation between immune response as a result of vitespen vaccination and potential clinical benefit," said Andrew T. Parsa, MD, PhD, assistant professor in the Department of Neurological Surgery at UCSF and recipient of the 2007 Young Investigator Award at AANS. "We are encouraged by the prolonged improvement in overall survival rates, although this phase 1/2 study is not designed to primarily evaluate efficacy. The patients in this trial represent the most challenging patient population to treat."

Of the 12 patients being treated, eight can currently be evaluated for overall survival, while four are still receiving treatment. Seven out of the eight patients have exceeded the historical median benchmark of 6.5 months survival from time of recurrence. The investigators will continue to follow the patients for overall survival. Based on these results, a larger, multi-center phase 2 study is planned for late 2007.

Derived from each individual's tumor, vitespen contains the "fingerprint" of the patient's particular cancer and is designed to reprogram the body's immune system to target only cancer cells bearing this fingerprint. The vaccine is intended to leave healthy tissue unaffected and limit the debilitating side effects typically associated with traditional cancer treatments such as chemotherapy and radiation therapy. Vitespen has been granted fast-track and orphan drug designations from the Food and Drug Administration for both metastatic melanoma (skin cancer) and renal cell carcinoma (kidney cancer).

Reviewing the presentation at AANS, Henry Brem, MD, director of neurosurgery at the Johns Hopkins Medical Institutions, noted, "This is an encouraging study of a therapeutic cancer vaccine that targets multiple tumor antigens, supported by rigorous immuno-monitoring. A larger phase 2 trial is certainly warranted to evaluate efficacy." Brem is a developer of the first approved local therapy for glioma.

The UCSF clinical trial is a phase1/2 study designed to establish the feasibility, safety and preliminary efficacy of vaccination in patients with recurrent, high-grade glioma. The trial involves two groups of six patients, both of whom receive a minimum of four injections. The first group receives biweekly vaccinations and the second receives weekly vaccinations. Patients are monitored for immune response before, during and after treatment.

The UCSF investigators will continue to follow patients for progression-

free survival and overall survival. According to investigators, no adverse events or toxicity identified were considered attributable to the vaccine.

Cheryl Canagelo, a 52-year-old woman from Oakley, Calif., came to UCSF for a second opinion after undergoing radiation and chemotherapy elsewhere for treatment of a glioma. At UCSF she learned that part of the tumor was still present, and she enrolled in the vitespen vaccine trial.

Once the chemotherapy was out of her system, Parsa performed surgery, just four days before Christmas. He removed all but a very small amount of tumor that was near an area that could affect her speech. The removed tissue was sent to Antigenics, the Massachusetts biotech company that produces the vaccine from the patient's tumor tissue. Altogether, Canagelo has now received seven injections of vaccine.

"My most recent MRI showed that there is no tumor," Canagelo said. "I haven't had any side effects from the treatment, and I'm getting stronger every day. I would urge patients to seek out second opinions and investigate clinical trials. I can tell you I am so glad I did."

"Our goal is to change the management of recurrent glioma from a life threatening disease, in which survival rates are typically 25 to 26 weeks, into a chronic disease with extended survival and improved quality of life for patients," Parsa said. "Although our survival data are encouraging, a larger phase 2 study will be required to determine the benefit of vitespen for patients with recurrent glioma. The consistent, tumor specific immune response seen in these patients suggests that in the right patient population, the vaccine could have a significant impact."

The clinical trial was funded by the American Brain Tumor Association and the National Cancer Institute's Specialized Program of Research Excellence.

Source: University of California - San Francisco

Citation: Brain tumor vaccine trial shows promising results (2007, April 16) retrieved 10 April 2024 from https://medicalxpress.com/news/2007-04-brain-tumor-vaccine-trial-results.html

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