

# Mayo Clinic tests novel vaccine for aggressive brain tumors

October 22 2007

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A vaccine that has significantly increased life expectancy in early tests of patients with glioblastoma multiforme (GBM) – the most common, most aggressive form of brain cancer in adults – is now being offered through a clinical trial at Mayo Clinic in Jacksonville.

The vaccine represents a fresh and fairly simple approach to treating this cancer, says neurosurgeon Kent New, M.D., Ph.D., who will be leading the study at Mayo. About 40% of these tumors display a particular protein on their surface and the vaccine is designed to trick the patient's immune system into thinking the protein is "foreign" in order to mount a killing response.

"We are pleased to have a new and promising therapy to offer patients who want to participate in this clinical trial," says Dr. New. "The results, so far, have exceeded expectations."

Earlier studies of the vaccine at the University of Texas M. D. Anderson Cancer Center and Duke University Medical Center showed that median survival for the 39 GBM patients tested increased by more than 50 percent compared to the typical outcome. Additionally, the time it took tumors to begin growing again was doubled.

Dr. New cautioned, however, that it is unknown whether the vaccine added to standard treatment (surgery followed by radiation and chemotherapy) will ultimately produce any better outcome than the standard treatment alone. "By comparing standard therapy plus the

vaccine to standard therapy alone, we hope to determine the true benefit of the vaccine” he says.

According to the National Cancer Institute, more than 20,000 people in the U.S. will be diagnosed with a brain tumor in 2007 and almost 13,000 will die from the cancer. GBM, the most common primary brain tumor, is considered incurable; most patients die within a year of diagnosis.

Twenty or more centers nationwide will participate in the clinical trial initially, which is being sponsored by Celldex Therapeutics, the manufacturer of the vaccine, known as CDX-110. The study will be conducted in two stages. Approximately 90 patients will participate in the first portion, and if results show an improvement in disease-free survival for the CDX-110 treated patients, an additional 285 participants will be enrolled in the expanded study, which will include more sites.

Patients newly diagnosed with GBM who enroll in the study will have surgery at the participating center, and tumors will be examined to see if they express the mutated epidermal growth factor receptor variant III (EGFRvIII) protein. Researchers believe that this protein, which is not expressed on normal brain cells, pushes cancer development, which is one reason why glioblastomas are so aggressive. The vaccine uses synthetic versions of EGFRvIII to stimulate both cell-mediated immunity (T cells that attack invaders) and humoral immune responses (B cells that provide ongoing immune surveillance).

Participating patients whose tumors exhibit EGFRvIII will be randomized (selected by chance) either to standard treatment alone or standard treatment plus CDX-110, and the agents will be used until the tumor progresses or patients develop side effects from the treatment.

Source: Mayo Clinic

Citation: Mayo Clinic tests novel vaccine for aggressive brain tumors (2007, October 22)  
retrieved 8 May 2024 from  
<https://medicalxpress.com/news/2007-10-mayo-clinic-vaccine-aggressive-brain.html>

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