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A PHASE I TRIAL OF TUMOR ASSOCIATED ANTIGEN-PULSED DENDRITIC CELL IMMUNOTHERAPY FOR PATIENTS WITH NEWLY DIAGNOSED AND RECURRENT GLIOBLASTOMA AND BRAIN STEM GLIOMA

The purpose of the Dendritic Cell Immunotherapy study for patients with glioblastoma and/or brainstem glioma is to determine whether in patients with malignant brain tumors, dendritic cells injected peripherally can reactivate the immune system against the brain tumor. Patients will have their white blood cells removed and grown in culture under conditions to make dendritic cells. Dendritic cells are a small group of cells that belong to the white blood cell population. These cells are responsible for letting the immune system know that something foreign, like bacteria or a tumor, is in the body. Dendritic cells help the body ward off disease by alerting the immune system. In previous clinical trials, brain tumor cells called astrocytoma tumor cells and glioblastoma tumor cells were taken from the tumor that was removed during surgery. The brain tumor cells were then placed into a solution in the laboratory that made them grow. Certain parts of the brain tumor's proteins (peptides) were removed from the growing tumor cells and mixed together with the dendritic cells in the blood taken from a vein. This combination of dendritic cells and brain tumor peptides were injected into the patient's skin, like a vaccination. This process is similar to that used in vaccinations. The patients were given three and four injections of dendritic cells mixed with the tumor peptides over the course of a twenty-eight day period.

In this study, the proteins that are manufactured and known to be associated with brain cancers will be mixed with the dendritic cells obtained during leukopheresis (a procedure in which the dendritic cells are separated from the patients' blood). They will then undergo three vaccinations along with follow up clinic visits (which include evaluations and laboratory tests) to check their status.

We learned that we were able to generate an immune response in a subset of patients with malignant glioma. In addition, these cells were able to reach the brain and kill brain tumor cells. The survival of patients in this study was prolonged when compared to historical controls. Based on clinical data in subjects with brain tumors, we believe that peripheral injection of dendritic cells will generate a more potent immune response for patients with brain stem gliomas and/or glioblastomas. We hope to determine whether this therapy will translate into a longer survival and better quality of life in these patients in whom survival is measured in months. Through this study we hope to learn more about the role of the body's immune response against cancer and about the use of dendritic cells for immunotherapy. This information may prove useful in the therapy of patients with glioblastoma and/or brainstem gliomas.

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