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A PHASE I TRIAL OF SURGICAL RESECTION WITH GLIADEL WAFER PLACEMENT FOLLOWED BY VACCINATION WITH DENDRITIC CELLS PULSED WITH TUMOR LYSATE FOR PATIENTS WITH MALIGNANT GLIOMA. (IRB# 9789)

Malignant gliomas are very aggressive and among the most common of brain tumors. A diagnosis carries with it a median survival of approximately 12 months, with 90-95% of patients surviving less than 2 years. The current standard treatment of surgical resection followed by radiation therapy and chemotherapy has not substantially prolonged survival and even the few treatment options shown to exhibit small increases in survival primarily benefit certain (i.e., young) patient subpopulations.

Cancer vaccines represent one novel therapy for malignant gliomas. The goal is for the body to recognize the tumor cells as foreign and produce its own response to fight off recurring tumor cells. A promising means of causing an immune response so the body can create this immunity is through the use of dendritic cell (DC) vaccines.

Dendritic cells are a small group of cells contained in everyone's 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.

Gliadel is an FDA-approved drug - a wafer containing a concentrated amount of a chemotherapy agent. These wafers are placed into the brain cavity after the tumor is resected (removed) and deliver a steady amount of immediate chemotherapy medicine to the surrounding brain tissue. Also, since Gliadel is a local chemotherapy, it will prevent the detrimental suppression (weakening) of the immune system shown with systemic (throughout the body) chemotherapy.

In prior Phase I and Phase II studies, patients who received chemotherapy following DC demonstrated longer progression free and overall survival than the patients who received DC or chemotherapy alone.

The purpose of this study is to determine whether after standard therapy of tumor resection surgery, along with placement of Gliadel wafers at time of surgery followed by DC vaccines will not only generate (start) an immune response, but will provide longer progression-free survival.

Patients who were screened and not enrolled in this clinical trial due to screen failure will be notified of the reason for screen failure. Pre HIV counseling and appropriate referral resources will be provided. If the screen failure is due to the positive HIV test, appropriate post HIV counseling will be provided and appropriate referrals will be made. The charts of the patients with screen failures will be destroyed. The patients' charts who will be enrolled in the study kept in the locked cabinet in the research office. Patients will be assigned a unique identifying code known only to the research team. Data will be captured by various source documents, or, as necessary, abstracted from hospital medical records by an experienced registered nurse. The electronic data for viral testing will be accessible to research personnel only.

The investigator will be responsible for all research-related costs as well as any injuries or adverse events deemed to be directly related to research-related procedures. A sponsor, MGI Pharma is providing approximately 80% financial support of the research-related procedures. The patient's insurance company will be responsible for costs that are considered standard of care - those that the patient would have regardless if he/she will be participating in a research study such as: surgery, blood tests, clinic visits and MRI scans.

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