MGI - Gliadel IRB CC429

Full Title
A Phase II, Multicenter, Exploratory Study, Evaluating the Treatment Effect of Surgery Plus GLIADEL Wafer in Patients with Metastatic Brain Cancer

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Objectives
1. The primary objective is to evaluate the effect of the surgical intervention and insertion of GLIADEL wafers on the neurocognitive functioning in patients with metastatic brain cancer.
2. The secondary objectives are to:
   • Evaluate the local recurrence rate of metastatic brain tumors;
   • Evaluate correlative science in metastatic lesions to the brain;
   • Determine the rate of neurological death defined as death attributable to the progression of neurological disease;
   • Determine the clinical significance (if any) of locally recurrent brain metastasis at the time of their occurrence (mass effect, cognitive functioning other symptoms) post treatment; and to Determine the time to and severity of neurocognitive decline in patients treated with GLIADEL.

Eligibility
Inclusion
In order to be included in this study, patients must meet all of the following criteria:
2. Are a male or female patient ≥18 years of age.
3. Are willing to use barrier method of contraception if fertile or of childbearing potential until 30 days after surgical resection. If the patient receives subsequent chemotherapy during study participation (as allowed by the protocol), appropriate contraception will be managed by the principal investigator.
4. Have a primary diagnosis of non-small cell lung cancer (NSCLC), breast, melanoma, renal, colon, or unknown primary cancer and have single brain metastasis for which surgical resection is planned; OR an intra-operative diagnosis of metastatic brain tumor in a patient with a single brain lesion.
5. Have a life expectancy of ≥12 weeks.
6. Have a Karnofsky Performance Status (KPS) score of 70 or higher.
7. Have Recursive Partitioning Analysis (RPA) status of 1 or 2.
8. Women of childbearing potential must have a negative serum or urine pregnancy test within 14 days of the surgical resection.
9. Patient must be able to understand English, either orally or in writing, and be able to consent and complete the required assessments and procedures.

Exclusions
Patients with any of the following are ineligible for this research study:
1. Are unable or unwilling to understand study assessment or to cooperate with the study procedures as determined by the investigator.
2. Have a history of allergic reaction or known hypersensitivity to BCNU (carmustine) or other components of the GLIADEL, such as polifeprosan polymer.
3. Have a history of prior cranial irradiation.
4. Have a prior diagnosis of CNS tumor.
5. Have received prior treatment for brain tumors.
6. Have had prior exposure to GLIADEL or its components, such as polifeprosan polymer.
7. Have any uncontrolled medical or psychiatric conditions which preclude them from participating in or completing the study procedures.
8. Concurrent severe medical conditions include, but are not limited to, active infection, acute hepatitis, cardiac arrhythmia, unstable angina, congestive heart failure, uncontrolled diabetes mellitus, uncontrolled seizures, pulmonary insufficiency, pulmonary fibrosis, pulmonary embolus, etc.
9. Have a diagnosis of tumor in the brain stem or posterior fossa.
11. Have a diagnosis of leptomeningeal disease at time of enrollment.
12. Are currently pregnant or lactating, or plan to become pregnant during the course of the study.