

Phase II Study of Conformal Radiotherapy in Patients with Low-Grade Gliomas (ACNS0221)

IRB# 2006-082

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Synopsis:

Primary objective:

To discover early compelling evidence that an unacceptable fraction of treatment failures are marginal failures as defined elsewhere in this document.

Secondary objectives:

To estimate the overall progression-free survival (PFS), event-free survival (EFS), and overall survival (OS) rates of pediatric patients with recurrent, progressive or symptomatic low-grade gliomas after treatment with reduced field conformal radiation, and within several well defined cohorts of these patients.

To measure the pre-treatment and post-treatment quality of life of these patients using a nurse administered battery of QOL instruments.

To determine if an elevated MIB-1 Labeling Index is associated with a shortened progression-free survival and overall survival for these patients.

Background: Low grade gliomas are the most common pediatric central nervous system malignancies. This group of tumors includes pilocytic and diffuse astrocytomas and also low-grade oligodendrogliomas and mixed tumors as well. They can occur in many different parts of the brain including the cerebellar and cerebral hemispheres as well as deeper midline structures. Patients for whom gross total resection has been accomplished (usually those with hemispheric tumors) have an excellent prognosis with surgical resection alone. Patients for whom gross total resection is not achievable, though, have a significant risk of disease progression and ultimate death from their tumors. These patients might, therefore, benefit from adjuvant therapy.

Radiation has been shown to be effective therapy in the treatment of these tumors. Because of concerns regarding radiation toxicity in young children, though, chemotherapy has been investigated intensively for patients less than 10 years old who have progressive or symptomatic low-grade gliomas. Recent developments in imaging and radiation therapy treatment planning and delivery have enabled radiation oncologists to deliver more conformal treatments, i.e., treatments for which the high dose region conforms to the shape of the intended target and surrounding normal structures are relatively spared. This protocol represents an attempt to measure the efficacy and safety of such treatments in a cooperative group setting.

Study Design: Patients with progressive or symptomatic low grade gliomas will be eligible for this study. Children under 10 years of age, though, must have received at least one prior course of chemotherapy before entering this study. All patients on the study will receive a course of external beam radiation to a dose of 54 Gy in 30 fractions delivered using conformal techniques to the tumor volume with tight margins. As these tumors often do not show up well on CT scans, MRI based treatment planning will be required. Any image-based treatment modality which can deliver treatment according to protocol specifications is allowed, e.g. 3D conformal, intensity-modulated radiation therapy (IMRT), stereotactic radiotherapy, and proton therapy.