

Head Start Protocol III: Dose Intensive Chemotherapy for Children less than 10 Years of Age Newly Diagnosed with Malignant Brain Tumors: A Study of Intensive Induction Chemotherapy followed by Consolidation with Myeloablative Chemotherapy (Thiotepa, Etoposide and Carboplatin) and Autologous Stem Cell Rescue with or without Subsequent Radiation Therapy for Patients with Medulloblastomas, other Primitive Neuroectodermal Tumors (PNET), Ependymoma, Choroid Plexus Carcinoma and Atypical Teratoid/Rhabdoid (AT/RT) Tumors.

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Synopsis:

Children less than 10 years of age at new diagnosis of malignant brain tumors may be eligible for this study. Following resection, children will undergo an evaluation of disease, brain MRI, spine MRI, CSF cytology, bone scan (if applicable). Pathology will be centrally reviewed, however, patients are eligible to start based on institutional pathology.

Patients will be randomized to Regimen C or D, based on histology. Medulloblastomas receive Regimen D; ependymoma received Regimen C; astrocytomas receive Regimen C; other non-astrocytic tumors received Regimen D.

Patients on Regimen D receive 5 cycles of chemotherapy using 3 cycles of cyclophosphamide, cisplatin, iv etoposide, vincristine, methotrexate and neupogen at 21 day intervals, alternating with 2 cycles of oral etoposide, oral temozolomide, vincristine and cyclophosphamide at 28 day intervals.

Patients on Regimen C receive 4 cycles of induction chemotherapy with 28 day intervals. Each cycle includes carboplatin, vincristine, temozolomide with neupogen.

Patients eligible to proceed to consolidation (persistent, non-recurrent residual tumor) will receive myeloablative chemotherapy followed by autologous stem cell rescue.

All children above 6 years of age will receive reduced dose radiation following recovery from consolidation phase of chemotherapy.

Children will be followed for both early and late effects of the tumor and therapy, including evaluation of neuropsychometric function, physical growth, pituitary function, auditory function, neurologic status as well as renal, hepatic, pulmonary, cardiac and immune function.

Patients will be evaluated for response by MRI, CSF and clinical evaluation.