ACNS2321; A Phase II Trial Evaluating Chemotherapy followed by Response-Based Reduced Radiation Therapy for Patients with Central Nervous System Germinomas

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Age: Patients must be ≥ 3 years and < 30 years at the time of study enrollment. Diagnosis: - Patients must be newly-diagnosed primary localized germinoma of the suprasellar and/or pineal region by pathology and/or serum and/or CSF hCGβ 5-50 mIU/mL AND institutional normal AFP (or ≤ 10 ng/mL if no institutional normal exists), including tumors with contiguous ventricular or unifocal parenchymal extension. No histologic confirmation required. - Patients with bifocal (pineal + suprasellar) involvement or pineal lesion with diabetes insipidus (DI) AND hCGβ ≤ 100 mIU/mL in serum and/or CSF AND institutional normal AFP (or ≤ 10 ng/mL if no institutional normal exists) in both serum and CSF. No histologic confirmation required. - Patients with hCGβ 51-100 mIU/mL in serum and/or CSF and institutional normal AFP (or ≤ 10 ng/mL if no institutional normal exists) in both serum and CSF. Histologic confirmation of germinoma IS required. - Patients with germinoma of the basal ganglia and or/thalamic primary sites are eligible. - Patients with metastatic germinoma including non-contiguous disease or distant disease in the brain, ventricles, or spine are eligible. - Patients with germinoma admixed with mature teratoma are eligible.

Exclusion Criteria:

- Patients with any of the following malignant pathological elements are not eligible: endodermal sinus (yolk sac), embryonal carcinoma, choriocarcinoma, malignant/immature teratoma and mixed GCT (i.e., may include some germinoma). - Patients with only mature teratoma upon tumor sampling at diagnosis and negative tumor markers are not eligible. - Patients who have received any prior tumor-directed therapy for their diagnosis of germinoma other than surgical intervention and corticosteroids are not eligible.

Conditions & Interventions

Interventions:
Radiation: 3-Dimensional Conformal Radiation Therapy, Procedure: Biospecimen Collection, Drug: Carboplatin, Drug: Etoposide, Radiation: Intensity-Modulated Radiation Therapy, Procedure: Lumbar Puncture, Procedure: Magnetic Resonance Imaging, Other: Questionnaire Administration, Procedure: Surgical Procedure
Conditions:
Brain & Nervous System, Cancer, Children's Health

More Information

Description: This study aims to reduce the radiotherapy (RT) dose necessary to successfully treat patients with intracranial germ cell tumors who are in a state of complete response (CR) following chemotherapy. In this study, a further reduction in whole ventricular irradiation (WVI) will be tested. The primary aim of the study is to determine whether 12 Gy of WVI, and 12 Gy tumor boost, would be successful. Event-free survival (EFS) in patients with central nervous system germinoma, who meet criteria for CR or continued complete response (CCR) following chemotherapy/second-look surgery, would be the primary measurement of success.
Study Contact: Allison Fullenkamp - fulle631@umn.edu
Principal Investigator: Clay Hoerig
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