ACNS1123: A Phase II Trial of Response-Based Radiation Therapy for Patients with Localized Central Nervous System Germ Cell Tumors.

PURPOSE: This phase II trial studies how well chemotherapy and radiation therapy work in treating younger patients with newly diagnosed central nervous system germ cell tumors.

Study Type: Interventional  
Masking: Open Label  
Primary Purpose: Treatment

AGES ELIGIBLE FOR STUDY: 3 Years to 21 Years

CRITERIA

DISEASE CHARACTERISTICS:

- Patients must be newly diagnosed with localized primary CNS nongerminomatous germ cell tumor (NGGCT) (Stratum 1) or localized primary CNS germinoma (Stratum 2); germ cell tumors (GCTs) located in the suprasellar, pineal, bifocal (pineal + suprasellar), and ventricles are eligible; tumors present in the above mentioned locations and with unifocal parenchymal extension are eligible
  
  o Stratum 1 (NGGCT): Patients must have one of the following criteria:
    - Patients with serum and/or CSF hCGβ > 100 mIU/mL or any elevation of serum and CSF alpha-fetoprotein (AFP) > 10 ng/mL or greater than the institutional normal are eligible, irrespective of biopsy results
    - Patients with any of the following elements on biopsy/resection are eligible, irrespective of serum and/or CSF hCGβ and AFP levels: endodermal sinus tumor (yolk sac), embryonal carcinoma, choriocarcinoma, malignant/immature teratoma, and mixed GCT with malignant GCT elements
  
  o Stratum 2 (Germinoma): Patients must have one of the following criteria:
    - Patients with institutional normal AFP AND hCGβ 5 to ≤ 50 mIU/mL in serum and/or CSF are eligible; no histologic confirmation required
    - Patients with bifocal (pineal + suprasellar) involvement or pineal lesion with diabetes insipidus AND hCGβ ≤ 100 mIU/mL and institutional normal AFP in serum and/or CSF are eligible; no histologic confirmation required
    - Patients with histologically confirmed germinoma or germinoma mixed with mature teratoma and hCGβ ≤ 100 mIU/mL and institutional normal AFP in serum and/or CSF are eligible
• Patients must have negative lumbar CSF cytology; lumbar CSF must be obtained unless medically contraindicated
• Patients must be enrolled on ALTE07C1 prior to enrollment on ACNS1123
• Patients with mature teratoma with normal tumor markers are not eligible
• Patients with tumors located outside the ventricles (basal ganglia, thalamus) are not eligible
• Patients with metastatic disease by either MRI evaluation or lumbar CSF cytology are not eligible

PATIENT CHARACTERISTICS:
• Peripheral absolute neutrophil count (ANC) ≥ 1,000/μL
• Platelet count ≥ 100,000/μL (transfusion independent)
• Hemoglobin ≥ 8.0 g/dL (may receive red blood cell [RBC] transfusions)
• Creatinine clearance or radioisotope GFR ≥ 70 mL/min/1.73 m² OR serum creatinine based on age/gender as follows:
  o 0.4 mg/dL (1 month to < 6 months of age)
  o 0.5 mg/dL (6 months to < 1 year of age)
  o 0.6 mg/dL (1 to < 2 years of age)
  o 0.8 mg/dL (2 to < 6 years of age)
  o 1.0 mg/dL (6 to < 10 years of age)
  o 1.2 mg/dL (10 to < 13 years of age)
  o 1.5 mg/dL (male) and 1.4 mg/dL (female) (13 to < 16 years of age)
  o 1.7 mg/dL (male) and 1.4 mg/dL (female) (≥ 16 years of age)
• Total bilirubin ≤ 1.5 times upper limit of normal (ULN)
• Serum glutamic oxaloacetic transaminase (SGOT) (aspartate aminotransferase [AST]) or serum glutamic pyruvate transaminase (SGPT) (alanine aminotransferase [ALT]) < 2.5 times ULN
• Patients with seizure disorder may be enrolled if well controlled
• Patients must not be in status, coma, or assisted ventilation prior to study enrollment
• Female patients who are pregnant are ineligible
• Lactating females are not eligible unless they have agreed not to breastfeed their infants
Female patients of childbearing potential are not eligible unless a negative pregnancy test result has been obtained.

Sexually active patients of reproductive potential are not eligible unless they have agreed to use an effective contraceptive method for the duration of their study participation.

PRIOR CONCURRENT THERAPY:

- Patients who had more than 1 prior surgery/biopsy are eligible.
- Patients must not have received any prior tumor-directed therapy other than surgical intervention and corticosteroids.

For more information contact:

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