A Study of Treatment for Medulloblastoma Using Sodium Thiosulfate to Reduce Hearing Loss

Status: RECRUITING

Eligibility Criteria

Age: 4 years to 21 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* PRE-ENROLLMENT: Patients must be ≥ 4 years and ≤ 21 years of age at the time of enrollment * PRE-ENROLLMENT: Patient is suspected to have newly-diagnosed medulloblastoma by institutional diagnosis * Please note: Patients with a pending result of CSF cytology tests are eligible for NCI-2014-02057 (APEC14B1-Central Nervous System \[CNS\]) and CNS/Medulloblastoma Pre Enrollment Eligibility Screening * PRE-ENROLLMENT: The patient and/or their parents or legal guardians must have signed informed consent for APEC14B1 Part A

•Eligibility Screening and consent for the Molecular Characterization Initiative (MCI) * PRE-ENROLLMENT: The required specimens are projected to be submitted under APEC14B1-CNS as soon as possible, preferably within 5 days of definitive surgery * PRE-ENROLLMENT: All patients must have rapid central pathology review under APEC14B1-CNS prior to study enrollment on ACNS2031 step 1 in order to avoid discordant diagnoses and to verify diagnosis criterion for treatment on ACNS2031. * Note: Patients with a pending result of CSF cytology tests are eligible for the rapid central pathology screening review. Confirmation of CSF negativity is needed for enrollment on the ACNS2031 protocol * PRE-ENROLLMENT: All patients must have rapid central molecular screening review under APEC14B1-CNS prior to study enrollment on ACNS2031 step 1, in order to avoid discordant diagnoses and to verify diagnosis criterion for treatment on ACNS2031 * PRE-ENROLLMENT: All patients who have histopathology confirmed must have rapid central imaging screening review under APEC14B1 prior to study enrollment on ACNS2031 step 1 * Note: Patients must not have metastatic disease on cranial or spinal MRI. Patients with \> 1.5 cm\^2 residual tumor after initial surgical resection may undergo a second surgical resection prior to subsequent therapy to render them eligible for this study. The day of the second resection to remove residual tumor will be regarded as the day of definitive surgery (Day 0) and must be within a month (31 days) of the initial resection * PRE-ENROLLMENT: All patients who have histopathology confirmed must have rapid central audiology review under APEC14B1-CNS prior to study enrollment on ACNS2031 step 1 * Patients must be \>= 4 years and =\< 21 years of age at the time of enrollment * Patients must be newly diagnosed and have eligibility confirmed by rapid central pathology and molecular screening reviews performed on APEC14B1 and via the Molecular Characterization Initiative * Average-risk cohort * Clinico-pathologic criteria: * M0 disease * No diffuse anaplastic histology AND * Molecular criteria: * SHH, p53wt, GLI2 normal, MYCN normal, no chromosome 14q loss * Group 3, MYC normal, no isochromosome 17q * Group 4, no chromosome 11 loss * Low-risk features cohort * Clinico-pathologic criteria: * M0 disease * No diffuse anaplastic histology AND * Molecular criteria: * Group 4, chromosome 11 loss * Patients must have negative lumbar CSF cytology * Note: CSF cytology for staging should be performed no sooner than 14 days post operatively to avoid false positive CSF. Ideally, CSF should be obtained between day 14 and day 21 to allow for final staging status before enrollment onto the study. Patients with positive CSF cytology obtained 0 to 14 days after surgery should have cytology repeated to determine eligibility and final CSF status. Patients with negative CSF cytology from lumbar puncture obtained 0 to 14 days after surgery do not need cytology repeated. Patients with negative CSF cytology from lumbar puncture obtained prior to surgery do not need cytology repeated post-operatively * Patients must have eligibility confirmed by Rapid Central Imaging Review performed on APEC14B1. Patients must have =\< 1.5 cm\^2 cross-sectional area of residual tumor. Whole brain MRI with and without gadolinium and spine MRI with gadolinium must be performed * Patients must weigh \> 10 kg * Patients must be enrolled, and protocol therapy must be projected to begin, no later than 31 days after definitive diagnostic surgery (day 0) * Peripheral absolute neutrophil count (ANC) \>= 1000/uL (within 7 days prior to enrollment) * Platelet count \>= 100,000/uL (transfusion independent) (within 7 days prior to enrollment) * Hemoglobin \>= 8.0 g/dL (may receive red blood cell count \[RBC\] transfusions) (within 7 days prior to enrollment) * A serum creatinine (within 7 days prior to enrollment) based on age/sex as follows: * 4 to \< 6 years (age); 0.8 mg/dL (male) 0.8 mg/dL (female) * 6 to \< 10 years (age); 1 mg/dL (male) 1 mg/dL (female) * 10 to \< 13 years (age); 1.2 mg/dL (male) 1.2 mg/dL (female) * 13 to \< 16 years (age); 1.5 mg/dL (male) 1.4 mg/dL (female) * \>= 16 years (age); 1.7 mg/dL (male) 1.4 mg/dL (female) OR a 24 hour urine Creatinine clearance \>= 70 mL/min/1.73 m\^2 (within 7 days prior to enrollment) OR a glomerular filtration rate (GFR) \>= 70 mL/min/1.73 m\^2 (within 7 days prior to enrollment). GFR must be performed using direct measurement with a nuclear blood sampling method OR direct small molecule clearance method (iothalamate or other molecule per institutional standard) * Note: Estimated GFR (eGFR) from serum creatinine, cystatin C or other estimates are not acceptable for determining eligibility * Total bilirubin =\< 1.5 x upper limit of normal (ULN) for age (within 7 days prior to enrollment) * Serum glutamic pyruvic transaminase (SGPT) (alanine aminotransferase \[ALT\]) =\< 135 U/L (within 7 days prior to enrollment) * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L * Central nervous system function defined as: * Patients with seizure disorder may be enrolled if on anticonvulsants and well controlled * Patients must not be in status epilepticus, a coma or assisted ventilation at the time of study enrollment * Auditory function defined as: * Patients must have normal hearing (defined as International Society of Pediatric Oncology \[SIOP\] grade 0) in at least one ear confirmed by rapid central audiology review performed on APEC14B1 prior to enrollment * All patients and/or their parents or legal guardians must sign a written informed consent * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

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Exclusion Criteria:

* Patients with metastatic disease by either MRI evaluation or lumbar CSF cytology are not eligible. Patients who are unable to undergo a lumbar puncture for assessment of CSF cytology are ineligible * Patients must not have received any prior radiation therapy or chemotherapy (tumor-directed therapy) other than surgical intervention and/or corticosteroids * Patients must not have any known hypersensitivity to STS, sulfates/sulfites, or other thiol agents (e.g., amifostine, n-acetylcysteine, MESNA, and captopril) * Pregnancy and Breastfeeding: * Female patients who are pregnant since fetal toxicities and teratogenic effects have been noted for several of the study drugs. A pregnancy test is required for female patients of childbearing potential * Lactating females who plan to breastfeed their infants * Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation

Conditions & Interventions

Interventions:

PROCEDURE: Audiometric Test, PROCEDURE: Auditory Brainstem Response, PROCEDURE: Biospecimen Collection, DRUG: Cisplatin, DRUG: Cyclophosphamide, DRUG: Lomustine, PROCEDURE: Magnetic Resonance Imaging, OTHER: Quality-of-Life Assessment, RADIATION: Radiation Therapy, DRUG: Sodium Thiosulfate, OTHER: Survey Administration, DRUG: Vincristine

Conditions:

Childhood Medulloblastoma

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE3

IRB Number:
System ID: NCT05382338

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