Targeted Pediatric High-Grade Glioma Therapy

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 months to 39 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Age: Patients must be ≥12 months and ≤39 years of age at the time of enrollment onto this screening protocol.
2. Diagnosis: Patients with newly diagnosed HGG, including DIPG are eligible. Diagnosis must have histologic confirmation from biopsy or resection. The diagnosis of HGG must have been confirmed by pathology review at the local site. For the diagnosis of DIPG, patients must have a tumor with pontine epicenter and diffuse involvement of at least 2/3 of the pons, with histopathology consistent with diffuse WHO grade 2-4 glioma (eg, diffuse astrocytoma, anaplastic astrocytoma, glioblastoma, H3K27-altered diffuse midline glioma). For all other tumors, histologic grade must be WHO grade 3-4.
3. Disease Status: There are no disease status requirements for enrollment.

- Measurable disease is not required. Patients without measurable disease are eligible.
- Patients with metastatic/disseminated or multifocal disease or gliomatosis cerebri are eligible.
- Patients with a primary spinal tumor are eligible.
- Patients with secondary, radiation related HGG are eligible.

    1. Prior Therapy for HGG: Surgery, radiation, and/or dexamethasone are permissible. Temozolomide concurrent with radiation is permissible. Prior administration of avastin/bevacizumab is allowed (individual treatment arms have different washout period requirements, check individual arm eligibility). No other prior anticancer therapy for HGG will be allowed.
- Participants screening for assignment to TarGeT-L may not have received radiation.

Timing from surgery to start of RT: For patients who have started RT, radiation must have started <42 days from definitive surgery or biopsy, however it is strongly recommended patients start RT within 31 days from definitive surgery (if patient had two surgeries, radiation must have started within 31 days from second surgery).
5. Tumor Sample Availability OR results from previous molecular profiling/targeted sequencing

- If a patient screens through OPTION #1, tumor sample in addition to normal comparator tissue (peripheral blood, saliva, or buccal swab) must be submitted for comprehensive molecular screening at the time of screening enrollment.
- If a patient screens through OPTIONS #2 or #3, results from previously performed molecular profiling must be submitted following enrollment. It is highly recommended that results be uploaded within 7 days of enrollment (if results are available at time of enrollment) or within 7 days of results becoming available (if pending at time of enrollment) to allow adequate time for central review.

    1. Informed Consent: All patients and/or their parents or legally authorized representatives must sign a written informed consent. Assent, when appropriate, will be obtained according to institutional guidelines.
    2. Enrollment timeline: Patients are eligible to enroll on the TarGeT-SCR anytime between diagnosis and the following specific timepoints post completion of RT (if relevant)
- Patients screening through OPTION #1 are eligible to enroll anytime between diagnosis and 10 days post RT (if completing RT).
- Patients screening through OPTIONS #2 or #3 are eligible to enroll anytime between diagnosis and 21 days post RT (if completing RT).
- Participants screening for TarGeT-L (lorlatinib) are eligible to enroll on TarGeT-SCR anytime between diagnosis and 31 days post definitive surgery (to allow time for molecular review).

However, it is important to note the following:

- For treatment protocols that include targeted therapy administered concurrently with RT, patients must start treatment within 10 calendar days of starting RT.
- For treatment protocols that only include maintenance/adjuvant therapy (no systemic therapy given concurrently with radiation), patients must start treatment by 35 days post RT

#SCREENING OPTIONS
* OPTION1: Molecular screening through CONNECT TarGeT Clinical Testing Laboratories
* OPTION2: Molecular screening through a national comprehensive tumor profiling program
* OPTION3: Clinically validated targeted sequencing or focused profiling

Exclusion Criteria:

-Tumors that do not meet HGG and DIPG diagnoses specified above

Conditions & Interventions

Conditions:
High Grade Glioma, Diffuse Intrinsic Pontine Glioma, Anaplastic Astrocytoma, Glioblastoma, Glioblastoma Multiforme, Diffuse Midline Glioma, H3 K27M-Mutant, Metastatic Brain Tumor, WHO Grade III Glioma, WHO Grade IV Glioma

K27M-Mutant, Metastatic Brain Tumor, WHO Grade III Glioma, WHO Grade IV Glioma

More Information

Description:
The goal of this study is to perform genetic sequencing on brain tumors from children, adolescents, and young adult patients who have been newly diagnosed with a high-grade glioma. This molecular profiling will decide if patients are eligible to participate in a subsequent treatment-based clinical trial based on the genetic alterations identified in their tumor.

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