Testing the Addition of an Anti-Cancer Drug, Triapine, to the Usual Radiation Therapy for Recurrent Glioblastoma or Astrocytoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have histologically, molecularly, or cytologically confirmed recurrent astrocytic tumors including: * GBM or variants, IDH-wildtype, grade 2-4 (standard curative measures available or not) * Astrocytoma, IDH-mutant, grade 2-4 (standard curative measures available or not) * Diffuse midline gliomas, including pediatric-type H3K G34 or E3 K27 mutant tumors. * Tumors ≤ 6 cm in maximal diameter. * Patients must have at least a 6-month break from last dose of radiation therapy. Re-irradiation within 6 months may increase risk for radiation necrosis/edema, which will affect toxicity assessment and patient safety. Additionally, GBM and other high-grade astrocytic tumors can exhibit pseudo-progression within 6 months from completing definitive, 1st line radiation therapy, and re-irradiation during this period will increase risk for misattribution of effect. * Prior history of standard dose radiation for gliomas of 59.4-60 gray (Gy) in 1.8-2 Gy per fraction (or equivalent or lower) is allowed. * Patients who received non-standard radiation dose regimen (e.g., 40 Gy, 34-35 Gy, 25 Gy) or stereotactic radiosurgery are eligible as long as there is at least one of the following: * A new tumor outside the original radiotherapy field as determined by the investigator. * There is histologic confirmation of tumor on biopsy or resection. * Imaging findings are consistent with true progressive disease (on standard MRI sequences, MRI spectroscopy/perfusion, or nuclear medicine imaging). * Age ≥ 18 years. Because no dosing or adverse event data are currently available on the use of triapine in patients \< 18 years of age, children are excluded from this study. * Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 (Karnofsky ≥ 60%). * Absolute neutrophil count ≥ 1,500/mcL. * Hemoglobin ≥ 8 g/dL. * Platelets ≥ 100,000/mcL. * Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN). * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) ≤ 3 x institutional ULN. * Creatinine ≤ 1.5 x ULN OR glomerular filtration rate (GFR) ≥ 50 mL/min/1.73 m\^2. * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load. * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial. * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class II or better. * Patients must be able to swallow whole capsules. * Patients must be able to undergo MRIs with contrast. Patients with non-compatible devices with MRI can be eligible if CT scans of sufficient quality are obtained. However, patients without non-compatible devices may not use CT scans to meet this requirement. * The effects of triapine on the developing human fetus are unknown. For this reason and because ribonucleotide reductase (RNR) inhibitor agent and radiation are known to be teratogenic, women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry, for the duration of study participation, and for 12 months after finishing study treatment. People of child-bearing potential must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of human chorionic gonadotropin \[HCG\]) within 2 weeks of registration. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately. Men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and 12 months after completion of triapine administration. * Ability to understand and the willingness to sign a written informed consent document. Legally authorized representatives may sign and give informed consent on behalf of study participants.

Exclusion Criteria:

* Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities \> grade 1) with the exception of alopecia. * Patients who are receiving any other investigational agents. * Patients who are actively taking medications that are known to induce methemoglobinemia (e.g. sulfonamides, nitrofurans, anti-malarials \[primaquine, chloroquine\], cyclophophsamide, and ifosfamide). * History of allergic reactions attributed to compounds of similar chemical or biologic composition to triapine. * Patients with known G6PD deficiency. Testing for G6PD deficiency is not required. * Patients with uncontrolled intercurrent illness, active infections, or any other significant condition(s) that would make participation in this protocol unreasonably hazardous. * Pregnant women are excluded from this study because triapine is a RNR inhibitor agent with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with triapine, breastfeeding should be discontinued if the mother is treated with triapine. These potential risks may also apply to the radiation used in this study.

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, RADIATION: Intensity-Modulated Radiation Therapy, PROCEDURE: Magnetic Resonance Imaging, DRUG: Triapine

Conditions:
Astrocytoma, IDH-Mutant, Grade 2, Recurrent Astrocytoma, IDH-Mutant, Recurrent Astrocytoma, IDH-Mutant, Grade 3, Recurrent Astrocytoma, IDH-Mutant, Grade 4, Recurrent Diffuse Midline Glioma, Recurrent Glioblastoma, IDH-Wildtype

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE1
IRB
Number:
System ID: NCT06860594
