

A Phase 3, multicenter, clinical study to evaluate the efficacy and safety of safusidenib erbumine in participants with isocitrate dehydrogenase 1 (IDH1)-mutant glioma (SIGMA)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 18 years of age or older - have a confirmed IDH1-mutant glioma that has returned, progressed, or meets the study-specific criteria for treatment - have received the required prior treatment for their type of glioma, which may include surgery, radiation therapy, chemotherapy, or other standard treatments - have measurable tumor remaining or recurring that can be seen on imaging - see link to [ClinicalTrials.gov](https://clinicaltrials.gov) for complete Inclusion criteria

Exclusion Criteria:

- prior treatment with certain medications targeting IDH1/IDH2 or other investigational treatments for glioma - tumor involves the brainstem or spinal cord, or there is evidence of cancer spread along the lining of the brain or spinal cord - significant medical, neurological, or heart conditions that could interfere with participation in the study - see link to [ClinicalTrials.gov](https://clinicaltrials.gov) for complete Exclusion criteria

Conditions & Interventions

Conditions:

Cancer

Keywords:

Clinics and Surgery Center (CSC), glioma, IDH1

More Information

Description: This study is evaluating safusidenib, an investigational oral medication, for people with certain types of IDH1-mutant glioma. The study has three parts and will examine how well safusidenib works, how safe it is, and how the body processes the medication. Depending on the type and stage of glioma, participants may receive safusidenib after standard treatment, safusidenib or placebo, or safusidenib following surgery.

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Phase: PHASE3

IRB Number: STUDY00028677

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