

COG ACNS1931 - A Phase 3 Study of Selumetinib (NSC# 748727, IND# 77782) or Selumetinib in Combination with Vinblastine for non-NF1, non-TSC Patients with Recurrent or Progressive Low-Grade Gliomas (LGGs) Lacking BRAFV600E or IDH1 Mutations

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Not specified

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- ages 2 to 21 at time of starting the study - diagnosis of low-grade glioma or low-grade astrocytoma brain tumor - tumor size increased or returned after treatment with at least one cancer therapy - high blood pressure (hypertension) must be under control - must be able to swallow whole capsules - contact study staff for additional criteria

Exclusion Criteria:

- treatment for another tumor in the past year - any serious medical or mental health diagnosis, including substance use disorders or ophthalmological conditions (study staff will review) - women who are pregnant or breast feeding

Conditions & Interventions

Interventions:

Procedure: Biospecimen Collection, Procedure: Magnetic Resonance Imaging, Other: Quality-of-Life Assessment, Other: Questionnaire Administration, Drug: Selumetinib Sulfate, Drug: Vinblastine Sulfate

Conditions:

Cancer

Keywords:

Astrocytoma, Glioma, Low Grade Astrocytoma, Low Grade Glioma

More Information

Description: This phase III trial investigates the best dose of vinblastine in combination with selumetinib and the benefit of adding vinblastine to selumetinib compared to selumetinib alone in treating children and young adults with low-grade glioma (a common type of brain cancer) that has come back after prior treatment (recurrent) or does not respond to therapy (progressive). Selumetinib is a drug that works by blocking a protein that lets tumor cells grow without stopping. Vinblastine blocks cell growth by stopping cell division and may kill cancer cells. Giving selumetinib in combination with vinblastine may work better than selumetinib alone in treating recurrent or progressive low-grade glioma.

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Phase: PHASE3

IRB Number: SITE00001839

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