



ONC201 for the Treatment of Newly Diagnosed H3 K27M-mutant Diffuse Glioma Following Completion of Radiotherapy: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified

This study is NOT accepting healthy

volunteers

Inclusion Criteria:

- body weight at least 10 kg (22 pounds) - new diagnosis of H3 K27M-mutant diffuse glioma - started radiotherapy within 12 weeks from the initial diagnosis - completed radiotherapy within 2 to 6 weeks prior to starting the study treatment - see link to clinicaltrials.gov for complete Inclusion and Exclusion criteria

Exclusion Criteria:

- primary spinal tumor - diffuse intrinsic pontine glioma (DIPG) - evidence of leptomeningeal spread of disease or cerebrospinal fluid dissemination - received whole-brain radiotherapy or proton therapy - study staff will review additional criteria

Conditions & Interventions

Interventions:

Drug: ONC201, Drug: ONC201 + Placebo, Other: Placebo

Conditions: Cancer Keywords:

Clinics and Surgery Center (CSC), Brain Cancer, Glioma, H3 K27M

More Information

Description: The study will test dordaviprone (also known as ONC201), a new drug that is being developed for treating people with glioma. ONC201 may help to remove tumor cells without affecting normal cells of the body. ONC201 is a first-in-class drug, which means it is a new drug having unique action.

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Number: STUDY00021033

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