PACIFIC NEUROSCIENCE INSTITUTE℠

JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

A Phase II Study of NovoTTF-200A Alone and With Temozolomide in Patients With Low-Grade Gliomas

Official Title: A Single-Center, Open-Lable, Randomized Phase II Study of NovoTTF-200A Alone and Combined With Temozolomide in Patients With Low-Grade Gliomas

The purpose of this study is to test the effectiveness and safety of the NovoTTF-200A device in patients with low-grade glioma when it's used by itself or used together with temozolomide.

NovoTTF-200A is a device that produces alternating electrical fields within the human body that disrupt cell division. These very low intensity intermediate frequency electric fields (TTFields) impair the growth of tumor cells through the arrest of cell division and inducing apoptosis.

Key Inclusion Criteria:

- Histologically confirmed low-grade glioma including astrocytoma grade 2, oligodendroglioma grade 2, or oligoastrocytoma grade 2.
- Tumor is supratentorially located and measureable.
- Disease that has not received prior radiation, radiosurgery, chemotherapy, or other investigational treatment directed at the brain tumor at any time. Previous surgical procedures is allowed.
- Age ≥ 18 years.
- Life expectancy > 12 weeks.
- Either not receiving steroids for disease symptoms or are on stable dose of steroids for at least 5 days.
- Karnofsky Performance Status (KPS) ≥ 60%

Key Exclusion Criteria:

- Pilocytic astrocytoma, ganglioglioma, pleomorphic xanthastrocytoma, or dysembryoplastic neuroepithelial tumors are not eligible.
- Current or anticipated use of other investigational agents.
- Implanted electronic medical device in the brain (e.g., deep brain stimulator, vagus nerve stimulator, programmable shunt).
- Patients who are less than 4 weeks from surgery or have insufficient recovery from surgical-related trauma or wound healing.
- Severe or uncontrolled medical disorder that would, in the investigator's opinion, impair ability to receive study treatment

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