

New Clinical Trials Open Up

The following is a list of some of the recent clinical trials that have begun recruiting and enrolling brain tumor patients to help evaluate new medicines and/or treatment approaches that could ultimately be beneficial to patients.

- **Cognitive Remediation Therapy for Brain Tumor Patients: Improving Working Memory**
 - **Description:** To investigate a computer-based Cognitive Remediation Therapy (CRT) for brain tumor patients at the Massey Cancer Center on measures of cognitive functioning (e.g., working memory, attention, processing speed, language, visuospatial functioning, immediate and delayed memory, or executive functioning) over time.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03323450>

- **A Phase 0/1 Exploratory Pharmacokinetic and Pharmacodynamics Study of Letrozole in Recurrent Gliomas**
 - **Description:** An early phase to see if the investigational drug Letrozole crosses the blood-brain-barrier and concentrates at the tumor.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03122197>

- **A Phase I Study of Ad-RTS-hIL-12, an Inducible Adenoviral Vector Engineered to Express hIL-12 in the Presence of the Activator Ligand Veledimex in Pediatric Brain Tumor Subjects**
 - **Description:** To study the safety and tolerability of a single tumor injection of the investigational treatment Ad-RTS-hIL-12 given with the oral drug veledimex in pediatric brain tumor (including DIPG) patients.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03330197>

- **A Phase 2 Study of Abemaciclib in Patients with Recurrent Brain Tumors**
 - **Description:** To study any good and/or bad effects of a study drug called Abemaciclib (LY2835219) in patients with recurrent brain tumors.
 - **LINKS:** <https://ClinicalTrials.gov/show/NCT03220646>

- **Feasibility Study of Modified Atkins Ketogenic Diet in the Treatment of Newly Diagnosed Malignant Glioma**
 - **Description:** To study if patients can produce ketones in their blood with the modified Atkins diet. Modified Atkins diet is a diet that produces ketones in your blood by restricting carbohydrates to <20 grams per day. Ketones are substances that are produced in the blood when fat is being broken down. Ketones may help radiation work better and may starve your tumor because it is thought that some brain tumors cannot use ketones to grow and can only use sugar or glucose to grow.
 - **LINKS:** <https://ClinicalTrials.gov/show/NCT03278249>

- **HUMC 1612: A Phase I Trial of the Optune NovoTTF-200A System With and Without Concomitant Temozolomide and Bevacizumab in Pediatric Patients With High-grade Glioma**

- **Description:** to determine if the Optune NovoTTF-200A device can be safely used in pediatric patients with high-grade glioma, both alone and in combination with standard chemotherapy medications.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03128047>
- **A Study of Pomalidomide (CC-4047) Monotherapy for Children and Young Adults With Recurrent or Progressive Primary Brain Tumors**
 - **Description:** A Phase 2 study that will assess the efficacy, safety and tolerability of pomalidomide in children and young adults aged 1 to < 21 years with recurrent or progressive primary brain tumors. The study will consist of 4 parallel groups, one for each of the following primary brain tumor types: high-grade glioma, medulloblastoma, ependymoma and DIPG.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03257631>
- **A Pivotal Randomized, Controlled Trial of VAL-083 in Patients With Recurrent Glioblastoma Who Have Failed Standard Temozolomide/Radiation Therapy and Bevacizumab (STAR-3)**
 - **Description:** This is an adaptive design, randomized controlled, Phase 3 clinical trial in patients with glioblastoma multiforme (GBM) or gliosarcoma (GS), previously treated with surgery (if appropriate), standard of care chemo-radiation with temozolomide, with or without adjuvant temozolomide, and bevacizumab and now has progressive disease during or after bevacizumab.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03149575>
- **Phase I/II Study of Oral Capecitabine and Temozolomide (CAPTEM) for Newly Diagnosed GBM**
 - **Description:** To evaluate the safety and efficacy of administering the medication capecitabine along with temozolomide when you start your monthly regimen of oral temozolomide for the treatment of your newly diagnosed glioblastoma multiforme (GBM). Capecitabine is an oral chemotherapy that is given to patients with other types of cancer. The study will evaluate whether the dosage of 1500 mg/m² of capecitabine is tolerable after radiation, when taken along with temozolomide. It will also try to determine if the medication capecitabine helps patients respond to treatment for a longer period of time compared to just temozolomide alone, which is the standard of care.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03213002>
- **Memantine for Prevention of Cognitive Late Effects in Pediatric Patients Receiving Cranial Radiation Therapy for Low-Grade Glioma: A Pilot Study**
 - **Description:** Children with brain tumors who have had radiation therapy are at risk for problems with attention, memory, and problem solving. Such problems may cause difficulty in school and daily life. Memantine, the drug being used for this study, is not yet approved for use in children by the U.S. Food and Drug Administration. However, studies have shown some improvements in memory for patients with dementia, Attention Deficit Hyperactivity Disorder, and autism. Scientists have also used this medication for adult cancer patients receiving radiation therapy with results showing less cognitive declines over time compared to patients taking a placebo (inactive pill). These studies have also

shown few side effects. This is a pilot/feasibility study and the first known study involving children with a cancer diagnosis or brain tumor.

- **LINK:** <https://ClinicalTrials.gov/show/NCT03194906>

- **A Phase 1/ 2 Study of the TRK Inhibitor LOXO 195 in Adult Subjects With NTRK Fusion (Previously Treated) or Non-Fusion NTRK Altered Cancers**
 - **Description:** This is a Phase 1/2, multi-center, open-label study designed to evaluate the safety and efficacy of LOXO-195 when administered orally to patients with NTRK fusion cancers (including a number of brain tumors) treated with prior TRK inhibition or non-fusion NTRK altered cancers regardless of prior kinase inhibitor treatment.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03215511>

- **A Phase II Trial of Immune Checkpoint Inhibitor Nivolumab in People With Select Rare CNS Cancers**
 - **Description:** This study will test whether the immunotherapy drug nivolumab is an effective treatment for adults with rare CNS tumors that have returned.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03173950>

- **A Phase 1b/2 Study to Assess the Safety, Tolerability and Efficacy of BGB-290 in Combination With Radiation Therapy (RT) and/or Temozolomide (TMZ) in Subjects With First-line or Recurrent/Refractory Glioblastoma**
 - **Description:** This study is to evaluate the safety, efficacy and clinical activity of BGB-290 in combination with radiation therapy (RT) and/or temozolomide (TMZ) in subjects with newly diagnosed or recurrent/refractory glioblastoma.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03150862>

- **Phase I Study of Tumor Treatment Fields and a Personalized Mutation-derived Tumor Vaccine in Patients With Newly Diagnosed Glioblastoma**
 - **Description:** The purpose of this study is to use precision medicine in the form of a vaccine, a mutation-derived tumor antigen vaccine (MTA-based vaccine) in combination with standard care treatment of glioblastoma (GBM) and Tumor Treating Fields (TTFields). The study is designed to determine whether this treatment combination is well tolerated and safe.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03223103>

- **An Online Dyadic Mind-Body Intervention for Glioma Patients and Their Partners**
 - **Description:** To examine the feasibility of the couple-based mind-body (CBMB) program in patients with high grade glioma (HGG) and their partners, as well as establish the initial efficacy of the CBMB program in patients and their partners regarding spiritual (primary), psychological and physical quality of life (QOL) (secondary) outcomes relative to a waitlist control (WLC) group.
 - **LINK:** <https://ClinicalTrials.gov/show/NCT03244995>