

Currently Active Trials (Newly Diagnosed Disease):

JAN. 2012

1. A Randomized, Double-blind, Controlled Phase IIb Study of the Safety and Efficacy of ICT-107 in Newly Diagnosed Patients with Glioblastoma Multiforme Following Resection and Chemoradiation
PI - Glantz
ClinicalTrials.gov - NCT01280552
PURPOSE: This is a phase 2, multicenter study to determine the safety and efficacy of ICT-107 in treating a type of brain tumor called Glioblastoma Multiforme (GBM). ICT-107 is an immunotherapy in which the patient's immune response will be stimulated to kill the tumor cells. The goal is for the ICT-107 vaccine to stimulate the patient's immune response to kill the remaining GBM tumor cells after surgery and chemotherapy.
2. PPX and Concurrent Radiation for Newly Diagnosed Glioblastoma Without MGMT Methylation: A Randomized Phase II Study: BrUOG 244
PI - Glantz
ClinicalTrials.gov - NCT01402063
PURPOSE: To obtain preliminary data in a randomized phase II study whether PPX/RT improves progression-free survival as compared to temozolomide/RT for patients with GBM without MGMT methylation.
3. Cilengitide in subjects with newly diagnosed glioblastoma multiforme and unmethylated MGMT gene promoter - a multicenter, open-label, Phase II study, investigating two cilengitide regimens in combination with standard treatment (temozolomide with concomitant radiation therapy, followed by temozolomide maintenance therapy)-CORE
PI - Glantz
ClinicalTrials.gov - NCT00813943
PURPOSE: CORE is a Phase II clinical trial in newly diagnosed glioblastoma multiforme (GBM) in patients with an unmethylated promoter of the methylguanine-DNA methyltransferase (MGMT) gene in the tumor tissue. In a safety run-in period in dedicated study centers the safety and tolerability of Cilengitide given as an intense treatment in combination with the first part of standard therapy will be assessed. Thereafter the trial will investigate the overall survival and progression-free survival in patients receiving two different regimens of Cilengitide in combination with standard treatment versus standard treatment alone.
4. A Phase 1 Dose Finding Study of the Safety and Pharmacokinetics of XL184 Administered Orally in Combination with Temozolomide and Radiation Therapy in the First Line Treatment of Subjects with Glioblastoma
PI - Glantz
ClinicalTrials.gov - NCT00960492
PURPOSE: The purpose of this study is to determine the highest safe dose of XL184 administered orally in combination with temozolomide and radiation therapy. XL184 is a new chemical entity that inhibits VEGFR2, MET, and RET, kinases implicated in tumor formation, growth and migration.

Currently Active Trials (Recurrent Disease):

1. A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma (RTOG 0929)
PI - Glantz
ClinicalTrials.gov - NCT01026493
PURPOSE: This randomized phase I/II trial is studying the side effects and best dose of giving ABT-888 together with temozolomide and to see how well it works in treating patients with recurrent glioblastoma.

Soon to Open Trials (Recruitment anticipated to begin in Spring 2012):

1. Open-label Phase 1/2 (Safety Lead-in) Study of Trans Sodium Crocetinate (TSC) with Concomitant Treatment of Fractionated Radiation Therapy and Temozolomide in Newly Diagnosed Glioblastoma (GBM) Patients to Evaluate Safety and Efficacy

PI - Sheehan

ClinicalTrials.gov - NCT01465347

PURPOSE: This open-label study will evaluate the safety and efficacy of TSC when dosed concomitantly with the standard of care (radiation therapy and temozolomide) for newly diagnosed glioblastoma in adults. All patients will receive TSC in the study. The objective of the study is to evaluate the effect of TSC on survival and tumor response in patients with GBM while establishing an acceptable patient risk profile.

Protocols in Development:

1. Phase I/II Trial of Intraventricular/Intrathecal Bevacizumab, plus standard Cranial Irradiation and Temozolomide, in Patients with Newly Diagnosed Glioblastoma Multiforme

PI- Glantz

This protocol is currently under development as an investigator initiated trial. More information will be available as it nears the recruitment phase.

For questions please contact Carla Baynham at 717-531-0003 x287366