Pivotal, Randomized, Open-label Study of Optune® (Tumor Treating Fields) Concomitant With RT & TMZ for the Treatment of Newly Diagnosed GBM

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Histologically confirmed diagnosis of GBM according to WHO classification criteria. 2. Age ≥ 22 years in US and Age ≥ 18 years in Ex-US 3. Recovered from maximal debulking surgery, if applicable (gross total resection, partial resection, and biopsy-only patients are all acceptable) 4. Planned treatment with RT/TMZ followed by TTFields and maintenance TMZ (150-200 mg/m2 daily x 5 d, q28 days) 5. Karnofsky performance status ≥ 70 6. Life expectancy ≥ least 3 months 7. Participants of childbearing age must use highly effective contraception. An effective method of birth control is defined as one that results in a failure rate of less than 1% per year when used consistently and correctly. The Investigator must approve the selected method, and may consult with a gynecologist as needed. 8. All patients must understand and voluntarily sign an informed consent document prior to any study related assessments/procedures being conducted. 9. Stable or decreasing dose of corticosteroids for the last 7 days prior to randomization, if applicable. 10. Concomitant RT with TMZ treatment planned to start no later than 8 weeks from surgery 11. Women of childbearing potential must have a negative β-HCG pregnancy test documented within 14 days prior to registration 12. Is able to have MRI with contrast of the brain

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Exclusion Criteria:

1. Progressive disease (per investigator's assessment) 2. Infratentorial or leptomeningeal disease 3. Participation in another clinical treatment study during the pre-treatment and/or the treatment phase of the study 4. Pregnancy or breast-feeding. 5. Significant co-morbidities at baseline which would preclude maintenance RT or TMZ treatment, as determined by the investigator: 1. Thrombocytopenia (platelet count < 100 x 103/µL) 2. Neutropenia (absolute neutrophil count < 1.5 x 103/µL) 3. CTC grade 4 non-hematological Toxicity (except for alopecia, nausea, vomiting) 4. Significant liver function impairment

•AST or ALT > 3 times the upper limit of normal 5. Total bilirubin > 1.5 x upper limit of normal 6. Significant renal impairment (serum creatinine > 1.7 mg/dL, or > 150 µmol/l) 7. History of any psychiatric condition that might impair patient's ability to understand or comply with the requirements of the study or to provide consent 6. Implanted pacemaker, defibrillator, deep brain stimulator, other implanted electronic devices in the brain, or documented clinically significant arrhythmias. 7. Evidence of increased intracranial pressure (midline shift > 5mm, clinically significant papilledema, vomiting and nausea or reduced level of consciousness) 8. History of hypersensitivity reaction to TMZ or a history of hypersensitivity to DTIC. 9. Any other cytotoxic or biologic anti-tumor therapy received prior to enrollment will be considered exclusion. 10. Admitted to an institution by administrative or court order. 11. Known allergies to medical adhesives or hydrogel 12. A skull defect (such as, missing bone with no replacement) 13. Prior radiation treatment to the brain for the treatment of GBM 14. Any serious surgical/post-operative condition that may risk the patient according to the investigator 15. Standard TTFields exclusion criteria include 1. Active implanted medical devices 2. Bullet fragments 3. Skull defects

Conditions & Interventions

Interventions:
Device: Optune®
Conditions:
Glioblastoma Multiforme
Keywords:
GBM

More Information

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IRB
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