Cleveland Clinic

Temozolomide +/- NovoTTF-100A for Newly Diagnosed GBM CC931/NOVO 1308

Full Title
A Prospective, Multi-center Trial of NovoTTF-100A Together With Temozolomide Compared to Temozolomide Alone in Patients with Newly Diagnosed GBM

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Eligibility
Inclusion

- Pathological evidence of GBM using WHO classification criteria.
- At least 18 years of age.
- Received maximal debulking surgery and radiotherapy with Temozolomide.
- Karnofsky scale at least 70.
- Life expectancy at least 3 months.
- Participants of childbearing age must use effective contraception.
- All patients must sign written informed consent.
- Treatment start date at least 4 weeks out from surgery.
- Treatment start date at least 4 weeks out but not more than 7 weeks from last dose of adjuvant Temozolomide.
- Treatment start date at least 4 weeks out from radiation therapy.

Exclusions

- Progressive disease (according to MacDonald Criteria).
- Actively participating in another clinical treatment trial
- Pregnant
- Significant co-morbidities at baseline which would prevent maintenance Temozolomide treatment:
    1. Thrombocytopenia (platelet count < 100,000/uL)
    2. Neutropenia (absolute neutrophil count < 1500/uL)
    3. CTDC 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 > upper limit of normal
    6. Significant renal impairment (serum creatinine > 1.7 mg/dL)
- Implanted pacemaker, defibrillator or deep brain stimulator, or documented clinically significant arrhythmias.
- Infra-tentorial tumor
- Evidence of increased intracranial pressure (midline shift > 5mm, clinically significant papilledema, vomiting and nausea or reduced level of consciousness)
- History of hypersensitivity reaction to Temozolomide or a history of hypersensitivity to DTIC.