A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Optune® (TTFields, 200 kHz) Concomitant with Maintenance Temozolomide and Pembrolizumab Versus Optune® Concomitant with Maintenance Temozolomide and Placebo for the Treatment of Newly Diagnosed Glioblastoma (EF-41/KEYNOTE D58)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- new diagnosis of Glioblastoma (GBM) - recovered from surgery (if done) - completed standard adjuvant chemoradiotherapy or radiotherapy (RT) with TMZ chemotherapy - may be to do physically strenuous activity but able to walk able to carry out work of a light or sedentary nature, e.g., light house work, office work - on stable or decreasing dose of corticosteroids

Exclusion Criteria:

- received prior therapy with an anti-Programmed Cell Death 1 (PD-1), anti- Programmed Cell Death-Ligand 1(PD-L1), or anti Programmed Cell Death-Ligand 2 (PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g.Cytotoxic T-Lymphocyte-Associated protein 4 (CTLA-4), OX 40, CD137) - diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy - known additional malignancy that is progressing or has required active treatment within the past 3 years

Conditions & Interventions

Interventions:
Device: Optune® device, Drug: Pembrolizumab, Drug: Placebo, Drug: Temozolomide
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Brain Cancer, Glioblastoma, new diagnosis of GBM

More Information

Description: The current study aims at testing the efficacy of concomitant temozolomide, Optune and pembrolizumab compared to concomitant temozolomide, Optune and placebo, following preclinical and clinical evidence demonstrating the potential augmentation of the immune response against glioblastoma under this regimen.
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