

Feasibility Study of Resection and GammaTile® Followed by Concomitant External Beam Radiation Therapy (EBRT) and Temozolomide (TMZ) and Adjuvant TMZ in Newly Diagnosed Glioblastoma (GBM).

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- newly diagnosed Glioblastoma (GBM) - plan for surgery to excise the tumor - cares for self; unable to carry on normal activity or work - able to understand English or Spanish - men and women of childbearing potential must be willing to use contraception throughout the study and for men for up to 3 months after completing treatment - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- known to have a IDH mutation glioma by prior biopsy - previous chemotherapy or radiotherapy to the head or neck region - prior invasive cancer (except non-melanoma skin cancer, cervical cancer in situ) unless disease free for a minimum of 2 years - contraindication to MRI or CT - women who are pregnant or breast feeding

Conditions & Interventions

Conditions:

Cancer, Rare Diseases

Keywords:

Clinics and Surgery Center (CSC), GBM, Glioblastoma

More Information

Description: The purpose of this research study is to evaluate the safety of GammaTile in combination with the Stupp Protocol for the treatment of newly diagnosed Glioblastoma. A GammaTile (GT) is an FDA cleared device used to provide radiation therapy following the removal of a brain tumor. GT are small (2cm x 2cm x 0.4cm) collagen squares/tiles that contain sources of radiation that look like grains of rice. The doctor will place tiles containing the radiation sources in the cavity left after surgically removing the brain tumor. They do not need to be removed as the collagen tiles will be absorbed by the body and the radiation sources can be left in place. The Stupp Protocol includes External Beam Radiation (EBRT) in combination with Temozolomide (TMZ) which is a chemotherapy drug. EBRT uses external beams to deliver radiation to the cavity left after surgical removal of a brain tumor. After the completion of EBRT/TMZ cycle additional treatment with TMZ will continue for 6 months.

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Phase: PHASE4

IRB

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