

A Phase 3 Randomized Controlled Trial of Post-Surgical Stereotactic Radiotherapy (SRT) versus Surgically Targeted Radiation Therapy (STaRT) with Gamma Tile for Treatment of Newly Diagnosed Metastatic Brain Tumors.

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- one to four newly diagnosed brain metastases, from an extracranial primary tumor (found on MRI) - planned surgery to remove one lesion is between 2.5 cm and 5.0 cm in size, other lesions must be less than 4.0 cm in size - able to complete an MRI of the head with contrast - fluent in English or Spanish language - additional criteria apply, contact study staff

Exclusion Criteria:

- past radiation or surgical therapy newly diagnosed lesion(s) - more than 4 newly diagnosed metastases on MRI - psychiatric, neurologic disease, injury impacting cognition

Conditions & Interventions

Interventions:

Device: Gamma Tile-Surgically Targeted Radiation Therapy (STaRT), Radiation: Stereotactic Radiation Therapy

Conditions:

Brain & Nervous System, Cancer

Keywords:

Brain Cancer, Clinics and Surgery Center (CSC)

More Information

Description: The purpose of this research study is to compare surgical tumor removal followed by stereotactic radiotherapy (SRT) to surgical tumor removal followed by radiation therapy delivered by surgically implanted GammaTilesTM (GT). 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. If assigned to the GT study group, 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 and the radiation sources can be left in place. If assigned to the SRT study group, SRT will take place 3-4 weeks after surgery and uses external beams to deliver radiation to the cavity left after surgically removing the brain tumor.

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Phase: PHASE3

IRB

Number: SITE00001150

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