A Phase 3, open-label, randomized 2-arm study comparing the clinical efficacy and safety of niraparib with temozolomide in adult participants with newly-diagnosed, MGMT unmethylated glioblastoma

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 intracranial Glioblastoma (GBM) - unmethylated MGMT promoter - no prior treatment for GBM (including brachytherapy or BCNU wafers), other than surgical resection or biopsy - not pregnant, planning to get pregnant, or breastfeeding - for participants of child bearing age, highly effective birth control is required - normal blood pressure (BP) or adequately treated and controlled hypertension (defined as systolic BP ≤140 mmHg and diastolic BP ≤90 mmHg) - able to swallow oral medications whole - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- metastatic or predominant leptomeningeal disease - Current active pneumonitis or any history of pneumonitis requiring steroids (any dose) or immunomodulatory treatment within 90 days of planned start of the study - gastrointestinal abnormalities that may alter absorption such as malabsorption syndrome or major resection of the stomach and/or bowels - cirrhosis or current unstable liver or biliary disease - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:
Drug: Niraparib, Drug: Temozolomide
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Brain Tumor, GBM, Glioblastoma

More Information

Description: This study compares treatment with niraparib to temozolomide in adult participants who have newly-diagnosed, MGMT unmethylated glioblastoma.
Study Contact: Elizabeth Neil - neile@umn.edu
Principal Investigator: Elizabeth Neil
Phase: PHASE3
IRB Number: STUDY00024466