Essai Clinique

Généré le 11 mai 2025 à partir de

Titre	A Phase II Trial of Concurrent Sunitinib, Temozolomide and Radiation Therapy followed by Adjuvant Sunitinib and Temozolomide for Newly Diagnosed Glioblastoma Patients with an Unmethylated MGMT Gene Promoter.
Protocole ID	SUTENT
ClinicalTrials.gov ID	NCT02928575
Type(s) de cancer	Cerveau (SNC)
Phase	Phase II
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
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Statut	Fermé
But étude	The purpose of this study is to determine whether a combination of Sunitinib, Temozolomide and Radiation Therapy would be effective in the treatment of newly diagnosed Glioblastoma patients harboring tumors with unmethylated MGMT promoter.
Critères d'éligibilité	• Histologically documented newly diagnosed GBM patients • Unmethylated MGMT promoter as determined by Methylation specific-polymerase chain reaction (MGMT(+) tumor) • Age between 18 to 70 • Karnofsky performance status ≥70 • History and physical examination including neurologic examination within 4 weeks prior to registration • Systolic blood pressure ≤ 160 mmHg or diastolic pressure ≤ 100mm Hg • Required blood work within 14 days prior to registration • Eligible for standard concurrent chemoradiation with TMZ • Patients must have normal organ and marrow functions as defined below: • Absolute neutrophil count ≥ 1.5x 109/L • Platelets ≥100x 109/L • Hemoglobin ≥80g/L • International Normalized Ratio ≤1.3 • Creatinine ≤1.5x [upper limit of normal] Or creatinine clearance ≥60 mL/min/1.73m2 • Normal baseline thyroid function as measured by a thyrotropic-stimulating hormone within institutional normal limits • Adequate liver function: Alanine transaminase or Aspartate transaminase < 2 x upper limit of normal and bilirubin 1.6 mg/dL. No active bleeding or pathologic condition that carries high risk of bleeding (e.g. tumor involving major vessels or known varices) • Patients who have undergone resection must meet the following conditions: • Patients must have recovered from the effects of surgery and a minimum of 14 to 28 days must have elapsed from the day of surgery to day of registration. Day of registration is considered the first day of Sunitinib. • For stereotactic biopsy, a minimum of 14 days must have elapsed prior to registration • No prior RT to the brain, chemotherapy, or anti-angiogenic therapy • Estimated life expectancy of at least 6 months • Premenopausal women must have a negative human chorionic gonadotropin within 14 days prior to registration • The effects of Sunitinib on the developing human fetus is unknown. Women of childbearing potential and male participants must practice adequate contraception. Should a woman become

	pregnant or suspect she is pregnant during the study, she should inform her treating physician immediately. • Ability to understand and the willingness to sign a written informed consent document
Critères d'exclusion	• Histologically documented newly diagnosed GBM patients with methylated MGMT promoter • Serious medical conditions that might be aggravated by treatment, including but not limited to: myocardial infarction within 6 months, congestive heart failure, unstable angina, active cardiomyopathy, unstable ventricular arrhythmia, uncontrolled hypertension, uncontrolled psychotic disorders, serious infections, active peptic ulcer disease, active liver disease or cerebrovascular disease with previous stroke • Patients with a history of coagulopathy • Evidence of intratumoural or peritumoural hemorrhage deemed significant by the treating physician • ≥ 1+ proteinuria on two successive urine dipstick assessments • thrombolytic therapy within 4 weeks • Patient with prolonged of corrected QT interval of more than 450 msec in screening EKG will be excluded • Women who are pregnant or nursing • History of allergic reactions attributed to compounds of similar chemical or biologic composition to Sunitinib • Previous treatment with Sunitinib or other inhibitors of the vascular endothelial growth factor signalling axis • Bleeding disorders • Concurrent use of anticoagulant or antiplatelet drugs • Patients with any condition that impairs their ability to swallow Sunitinib (e.g. gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for IV alimentation, prior surgical procedures affecting absorption, or active peptic ulcer disease). • HIV-positive patients on combination antiretroviral therapy are ineligible because of the potential for pharmacokinetic interactions with Sunitinib. In addition, these patients are at increased risk of lethal infections when treated with bone marrow-suppressive therapy • Individuals with MRI non-compatible metal in the body, or unable to undergo MRI procedures. • Allergy to gadolinium • Patients with severe liver impairment will not be enrolled in this study.