Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	Étude randomisée de phase II avec escalade de dose hypofractionnée en photons par IMRT ou par faisceau de protons vs de l'irradiation par photons conventionnelle en association avec du Temozolomide concomitant en adjuvant chez les patients présentant un glioblastome multiforme nouvellement diagnostiqué
Protocole ID	BN001
ClinicalTrials.gov ID	NCT02179086
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
Date d'activation	18-02-2015
But étude	This randomized phase II trial studies how well dose-escalated photon intensity-modulated radiation therapy (IMRT) or proton beam radiation therapy works compared with standard-dose radiation therapy when given with temozolomide in patients with newly diagnosed glioblastoma. Radiation therapy uses high-energy x-rays and other types of radiation to kill tumor cells and shrink tumors. Specialized radiation therapy that delivers a high dose of radiation directly to the tumor may kill more tumor cells and cause less damage to normal tissue. Drugs, such as temozolomide, may make tumor cells more sensitive to radiation therapy. It is not yet known whether dose-escalated photon IMRT or proton beam radiation therapy is more effective than standard-dose radiation therapy with temozolomide in treating glioblastoma.
Critères d'éligibilité	• A diagnostic contrast-enhanced magnetic resonance imaging (MRI) (no other scan type allowed) of the brain must be performed postoperatively within 72 hours of resection; the enhancing tumor must have a maximal diameter of 5 cm; the tumor diameter will be the greatest diameter as measured on the contrast-enhanced postoperative MRI and will include residual disease and/or the postoperative surgical cavity as appropriate; for cases where residual disease or postoperative surgical cavity is NOT identifiable (e.g., polar glioblastomas [GBMs] where a polar lobectomy is performed), the patient will be excluded from the trial • The GBM tumor must be located in the supratentorial compartment only (any component involving the brain stem or cerebellum is not allowed) • Histologically proven diagnosis of glioblastoma (World Health Organization [WHO] grade IV) confirmed by central review • Tumor tissue that is determined by central pathology review registration to be of sufficient quantity for analysis of O6-methylguanin-DNA-methyltransferase (MGMT) status • Patients must have at least 1 block of tumor tissue; submission of 2 blocks is strongly encouraged to maximize the chances of eligibility; at least 1 cubic centimeter of tissue composed primarily of tumor must be present • Diagnosis must be made by surgical excision, either partial or complete; stereotactic biopsy or cavitron ultrasonic suction aspirator (CUSA) technique are not allowed • History/physical examination within 14 days prior to registration • The patient must have recovered from effects of surgery, postoperative infection, and other complications within 14 days prior to registration • Documentation of steroid doses within 14 days prior to registration • Karnofsky performance status >= 70 within 14 days prior to registration

	• Age >= 18 • Absolute neutrophil count (ANC) >= 1,800 cells/mm^3 • Platelets >= 100,000 cells/mm^3 • Hemoglobin >= 10.0 g/dl (note: the use of transfusion or other intervention to achieve hemoglobin (Hgb) >= 10.0 g/dl is acceptable) • Bilirubin =< 1.5 upper limit of normal (ULN) • Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) =< 3 x ULN • CD4 lymphocyte count within 14 days prior to registration • Negative serum pregnancy test obtained for females of child-bearing potential within 14 days prior to registration
Critères d'exclusion	• Prior invasive malignancy (except non-melanomatous skin cancer) unless disease-free for a minimum of 3 years; (for example, carcinoma in situ of the breast, oral cavity, or cervix are all permissible) • Recurrent or multifocal malignant gliomas • Any site of distant disease (for example, drop metastases from the GBM tumor site) • Prior chemotherapy or radiosensitizers for cancers of the head and neck region; note that prior chemotherapy for a different cancer is allowable (except temozolomide) • Prior use of Gliadel wafers or any other intratumoral or intracavitary treatment are not permitted • Prior radiotherapy to the head or neck (except for T1 glottic cancer), resulting in overlap of radiation fields • Severe, active co-morbidity, defined as follows: • Unstable angina • Transmural myocardial infarction within the last 6 months • Evidence of recent myocardial infarction or ischemia by the findings of S-T elevations of >= 2 mm using the analysis of an electrocardiogram (EKG) • New York Heart Association grade II or greater congestive heart failure requiring hospitalization within 12 months prior to registration • Serious and inadequately controlled arrhythmia • Serious or non-healing wound, ulcer or bone fracture or history of abdominal fistula, intra-abdominal abscess requiring major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to registration, with the exception of the craniotomy for surgical resection • Acute bacterial or fungal infection requiring intravenous antibiotics • Hepatic insufficiency resulting in clinical jaundice and/or coagulation defects; note, however, that laboratory tests for coagulation parameters are not required for entry into this protocol • Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy • Acquired immune deficiency syndrome (AIDS) based upon current Centers for Disease Control and Prevention (CDC) definition; note, however, that human immunodeficiency virus (HIV) testing is not required for entry into this protocol • Any other severe immunocompromised condition • Active connective tissue disorders, such as lupus or scleroderma, that in the opinion of the treating physician may put the patient at high risk for radiation toxicity • End-stage renal disease (ie, on dialysis or dialysis has been recommended) • Any other major medical illnesses or psychiatric treatments that in the investigator's opinion will prevent administration or completion of protocol therapy • Pregnancy or women of childbearing potential and men who are sexually active and not willing/able to use medically acceptable forms of contraception • Patents treated on any other therapeutic clinical protocols within 30 days prior to registration • Inability to undergo MRI (e.g., due to safety reasons, such as presence of a pacemaker, or severe claustrophobia)