Essai Clinique

Généré le 11 mai 2025 à partir de

Titre	Étude intergroupe de la phase III portant sur la combinaison radiothérapie et témozolomide concomitant et adjuvant par rapport à une chimiothérapie PCV adjuvante administrée à des patients qui ont un gliome anaplasique ou de bas grade avec la codélétion 1p/19q.
Protocole ID	CEC.6
ClinicalTrials.gov ID	NCT00887146
Type(s) de cancer	Cerveau (SNC)
Phase	Phase III
Type étude	Traitement
Médicament	témozolomide
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dre Laura Masucci
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Statut	Fermé
Date d'activation	29-11-2016
But étude	Radiation therapy uses high-energy x-rays to kill tumor cells. Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether giving radiation with concomitant and adjuvant temozolomide versus radiation with adjuvant PCV is more effective in treating anaplastic glioma or low grade glioma.
Critères d'éligibilité	• Age ≥ 18 years • Newly diagnosed and ≤ 3 months from surgical diagnosis • Histological confirmation of anaplastic glioma (oligodendroglioma, mixed, or astrocytoma [WHO grade 2 or 3] or low grade glioma [WHO grade 2], as determined by pre-registration central pathology review. Note: Mixed gliomas are eligible, regardless of the degree of astrocytic or oligodendrocytic predominance, as long as the tumor is also co-deleted for 1p and 19q. • Patients with codeleted low grade gliomas must also be considered "high risk" by clinical criteria utilized in RTOG 9802 and must be either: age ≥ 40 and any surgical therapy or age < 40 and subtotal resection or biopsy. • Tumor tissue must show co-deletion for the relevant portions of chromosomes 1p and 19q by FISH analysis, as defined by the testing laboratory. • Surgery (partial or gross total resection or biopsy) must be performed ≥ 2 weeks prior to registration. Patient must have recovered from the effects of surgery. • The following laboratory values obtained ≤ 21 days prior to registration. • Absolute neutrophil count (ANC) ≥ 1500/mm^3 • Platelet (PLTs) count ≥ 100,000/mm^3 • Hemoglobin (Hgb) > 9.0g/dL • Total bilirubin ≤ 1.5 x upper limit of normal (ULN) • Serum glutamic oxaloacetic transaminase (SGOT) aspartate transaminase (AST) ≤ 3 x ULN • Creatinine ≤ 1.5 x ULN • Negative serum or urine pregnancy test done ≤ 7 days prior to registration for women of childbearing potential only. • Willing and able to complete neurocognitive testing without assistance and the Quality of Life (QOL) questionnaires with or without assistance

	• Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2 • Provide informed written consent. • Willing to return to enrolling institution for follow-up during the Active Monitoring Phase (ie, active treatment and observation portion) of the study • Mandatory Tissue Samples for Correlative Research -Patient willing to provide tissue samples for correlative research purposes
Critères d'exclusion	• Fetal/Newborn Toxicity: Any of the following because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects: Pregnant women, nursing women, men or women of childbearing potential who are unwilling to employ adequate contraception during this study and for up to 6 months following the completion of temozolomide treatments. • Received any prior surgery, radiation therapy or chemotherapy for any central nervous system (CNS) neoplasm. Note: Patients who have had a prior low grade glioma with or without surgery and who now have anaplastic glioma with no prior radiation or chemotherapy are eligible for the study. • Co-morbid systemic illnesses or other severe concurrent disease which, in the judgment of the investigator, would make the patient inappropriate for entry into this study or interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens. • Concomitant serious immunocompromised status (other than that related to concomitant steroids) that would compromise the safety of the patient on the study. • Patients known to be Human Immunodeficiency Virus (HIV) positive and currently receiving retroviral therapy. Note: Patients known to be HIV positive, but without clinical evidence of an immunocompromised state, are eligible for the study. • Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements. • Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm. • Other active malignancy within 5 years of registration. Exceptions: Non-melanotic skin cancer or carcinoma in situ of the cervix. Note: If there is a history of prior malignancy, the patient must not be receiving other specific treatment (other than hormonal therapy) for their cancer. • History of myocardial infarction ≤ 6 months, or congestive heart failure requiring use of ongoing maintenance therapy for life-threatening ventricular arrhythmias. • Recent history of hepatitis infection or treating physician determined that the patient would be at significant risk of reactivation of hepatitis.