Essai Clinique

Généré le 29 mars 2024 à partir de

Titre	Essai de phase III sur l'emploi du marizomib en association avec une radiochimiothérapie standard à base de témozolomide par rapport à une radiochimiothérapie standard à base de témozolomide administrée seule chez des patients ayant reçu un diagnostic récent de glioblastome
Protocole ID	CE.8
ClinicalTrials.gov ID	NCT03345095
Type(s) de cancer	Cerveau (SNC)
Phase	Phase III
Stade	Première intention de traitement
Type étude	Traitement
Médicament	Marizomib avec radiochimiothérapie à base de Temozolomide
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
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Statut	Fermé
Date d'activation	28-09-2018
But étude	The standard of care for newly diagnosed glioblastoma includes surgery, involved-field radiotherapy, and concomitant and six cycles of maintenance temozolomide chemotherapy, however the prognosis remains dismal. Marizomib has been tested in patients with newly diagnosed and recurrent glioblastoma in phase I and phase II studies. In patients with recurrent glioblastoma, marizomib was administered as a single agent or in combination with bevacizumab (NCT02330562). Based on encouraging observations, a phase I/II trial of marizomib in combination with TMZ/RT -->TMZ in newly diagnosed glioblastoma has been launched (NCT02903069) which explores safety and tolerability of this triple combination and which shall help to determine the dose for further clinical trials in glioblastoma. In this context, given that marizomib has been established as a safe addition to the standard TMZ/RT -->TMZ, a phase III study is considered essential to establishing its impact on overall survival.
Critères d'éligibilité	• Histologically confirmed newly diagnosed glioblastoma (WHO grade IV) • Tumor resection (gross total or partial), or biopsy only • Availability of FFPE tumor block or 24 unstained slides for MGMT analysis • Patient must be eligible for standard TMZ/RT + TMZ • Karnofsky performance score (KPS) ≥ 70 • Recovered from effects of surgery, postoperative infection and other complications of surgery (if any) • The patient is at least 18 years of age on day of signing informed consent • Stable or decreasing dose of steroids for at least 1 week prior to inclusion • The patient has a life expectancy of at least 3 months • Patient has undergone a brain MRI within 14 days of randomization but after intervention (resection or biopsy) • The patient shows adequate organ functions as assessed by the specified laboratory values within 2 weeks prior to randomization defined as adequate bone marrow, renal and hepatic function within the following ranges:

	• WBC ≥ 3×10*9/L • ANC ≥ 1.5×10*9/L • Platelet count of ≥ 100×10*9/L independent of transfusion • Hemoglobin ≥ 10 g/dl • Total Bilirubin ≤ 1.5 ULN • ALT, AST, alkaline phosphatase (ALP) ≤ 2.5 × ULN • Serum creatinine < 1.5 x ULN or creatinine clearance (CrCl) > 30 mL/min(using the Cockcroft-Gault formula) • Women of child bearing potential (WOCBP) must have a negative urine or serum pregnancy test within 7 days prior to the first dose of study treatment. • Patients of childbearing / reproductive potential must agree to use adequate birth control measures, as defined by the investigator, during the study treatment period and for at least 6 months after the last study treatment. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1 percent per year) when used consistently and correctly. Patients must also agree not to donate sperm during the study and for 6 months after receiving the last dose of study treatment. • Women who are breast feeding must agree to discontinue nursing prior to the first dose of study treatment and until 6 months after the last study treatment. • Ability to take oral medication • Ability to understand the requirements of the study, provide written informed consent and authorization of use and disclosure of protected health information, and agree to abide by the study restrictions and return for the required assessments. • Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations.
Critères d'exclusion	