Essai Clinique

Généré le 25 avr. 2024 à partir de

Titre	Étude ouverte de phase III à répartition aléatoire visant à comparer l'efficacité et l'innocuité de l'association de l'éflornithine et de la lomustine à celles de la lomustine en monothérapie dans le traitement de patients atteints d'un Astrocytome anaplasique ayant progressé ou récidivé après une radiothérapie et une chimiothérapie adjuvante à base de témozolomide
Protocole ID	Orbus OT-15-0011
ClinicalTrials.gov ID	NCT02796261
Type(s) de cancer	Cerveau (SNC)
Phase	Phase III
Médicament	Eflornithine + Lomustine
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL HOPITAL NEUROLOGIQUE DE MONTREAL 3801 Rue Université, Montréal, QC, H3A 2B4
Ville	Montréal
Investigateur principal	Dr Kevin Petrecca
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Statut	Actif en recrutement
But étude	The purpose of this study is to compare the efficacy and safety of eflornithine in combination with lomustine, compared to lomustine taken alone, in treating patients whose anaplastic astrocytoma has recurred/progressed after radiation and temozolomide chemotherapy.
Critères d'éligibilité	• Patients must meet all of the following inclusion criteria to be eligible for participation in this study: • Surgical or biopsy-proven diagnosis of WHO grade 3 AA. • Unequivocal evidence of first AA tumor progression or recurrence ≤ 3 months prior to randomization based on MRI criteria for tumor progression using enlarging Gd-contrast enhancement and/or T2 hyperintensity. Patients with non-measurable Gd contrast enhancing tumors will only be eligible if there is no necrosis seen on MRI and/or histopathological confirmation of AA per standard of care procedures is obtained. • First tumor progression or recurrence following surgical resection or biopsy, if resection is not feasible, EBRT and temozolomide chemotherapy. • Completion of EBRT ≥ 6 months prior to randomization. • A patient whose AA tumor has progressed or recurred and has had another surgical resection prior to randomization will be eligible if a) pathology review confirms AA, and b) post-surgical MRI demonstrates measurable tumor on T2/FLAIR. • Karnofsky Performance Status (KPS) score of ≥ 70.
Critères d'exclusion	• Patients who meet any of the following exclusion criteria are not eligible for study participation: • MRI defining progression is consistent with a diagnosis of glioblastoma or radiation necrosis. • Patients who are considered to be refractory to EBRT and temozolomide but who have not progressed. • Prior systemic therapy for recurrence of AA. • Presence of extracranial or leptomeningeal disease. • Prior lomustine use. • Any other clinical condition or prior therapy that, in the opinion of the Investigator, would make the patient unsuitable for the study. • Pregnant or breastfeeding.