Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Essai de phase III multicentrique avec répartition aléatoire sur la radiothérapie peropératoire dans le cas du glioblastome multiforme nouvellement diagnostiqué
Protocole ID	INTRAGO II
ClinicalTrials.gov ID	NCT02685605
Type(s) de cancer	Cerveau (SNC)
Phase	Phase III
Type étude	Traitement
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL HOPITAL NEUROLOGIQUE DE MONTREAL 3801 Rue Université, Montréal, QC, H3A 2B4
Ville	Montréal
Investigateur principal	Dr Kevin Petrecca
Coordonnateur	Gabriele Riva 514-398-6907
Statut	Actif en recrutement
But étude	INTRAGO II s'apparente à un essai clinique ouvert de phase III, multicentrique, prospectif, avec répartition aléatoire, à deux groupes, qui vérifie si la survie sans progression (SSP) médiane des patients atteints d'un glioblastome multiforme (GBM) nouvellement diagnostiqué peut être améliorée par l'ajout d'une radiothérapie peropératoire à la radiochimiothérapie standard.
Critères d'éligibilité	1. Age ≥18 and ≤ 70 years (≤ 75 years after amendement 3) 2. Karnofsky Performance Score (KPS) ≥ 60% 3. Supratentorial T1-Gd enhancing lesion(s) amenable to total resection 4. Legal capacity and ability of subject to understand character and individual consequences of the clinical trial 5. Patient's written informed consent obtained at least 24h prior to surgery 6. For women with childbearing potential: adequate contraception 7. Patients must have adequate organ functions Bone marrow function: • Platelets ≥ 145.000/µL • WBC ≥ 4.000/µL • Hemoglobin ≥ 12.0 g/dL Liver Function: • ASAT and ALAT ≤ 1.5 times ULN • ALP ≤ 2.5 times ULN • Total Serum Bilirubin < 1 times ULN Renal Function: • Serum Creatinine ≤ 1.5 times ULN Inclusion Criteria Related to Surgery: 8. IORT must be technically feasible 9. Histologically confirmed (frozen section) GBM (WHO grade IV)
Critères d'exclusion	• Multicentric disease (e.g. in both hemispheres) or non-resectable satellite lesions • Previous cranial radiation therapy • Cytostatic therapy / chemotherapy for cancer within the past 5 years • History of cancers or other comorbidities that limit life expectancy to less than five years • Previous therapy with anti-angiogenic substances (such as bevacizumab) • Technical impossibility to use MRI or known allergies against MRI and/or CT contrast agents • Participation in other clinical trials testing cancer-derived investigational agents/procedures. • Pregnant or breast feeding patients

- Fertile patients refusing to use safe contraceptive methods during the study
- Exclusion Criteria Related to Surgery:
- Active egress of fluids from a ventricular defect
- In-field risk organs and/or IORT dose >8 Gy to any risk organ