Essai Clinique

Généré le 06 mai 2024 à partir de

Titre	Essai randomisé de phase III de la chimiothérapie après une radiothérapie chez des patients de 1 à 21 ans atteints d'un épendymome qui vient d'être diagnostiqué
Protocole ID	COG-ACNS0831
ClinicalTrials.gov ID	NCT01096368
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Type étude	Traitement
Médicament	chimiothérapie de maintenance
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
Investigateur principal	Dr Yvan Samson
Coordonnateur	Linda Hershon 514-345-4931 poste 5899
Statut	Fermé
But étude	This randomized phase III trial is studying maintenance chemotherapy to see how well it works compared to observation following induction chemotherapy and radiation therapy in treating young patients with newly diagnosed ependymoma.

Critères d'éligibilité	DISEASE CHARACTERISTICS:
	• Histologically confirmed intracranial ependymoma meeting the following criteria:
	  • Newly diagnosed disease
	  • Classic ependymoma (WHO II) or anaplastic ependymoma (WHO III), including the following subtypes:
	  • Clear cell
	  • Papillary
	  • Cellular
	  • Combination of the above
	• No diagnosis of spinal cord ependymoma, myxopapillary ependymoma, subependymoma, ependymoblastoma, or mixed glioma
	• Has undergone surgical resection of the primary tumor
	  • More than 1 attempted resection allowed
	• No metastatic disease by MRI or cerebrospinal fluid (CSF) cytology
	  • CSR cytology from a ventriculostomy or permanent VP shunt that reveals the presence of tumor cells is indicative of metastatic disease
	• No evidence of non-contiguous spread beyond the primary site as determined by pre- or post-operative MRI of brain, pre- or post-operative MRI of the spine, and post-operative CSF cytology obtained from the lumbar CSF space
	  • Lumbar CSF examination may be waived if deemed to be medically contraindicated
	PATIENT CHARACTERISTICS:
	• ECOG performance status (PS) 0-2
	  • Karnofsky PS for patients > 16 years of age
	  • Lansky PS for patients ≤ 16 years of age
	• ANC ≥ 1,000/μL
	• Platelet count ≥ 100,000/μL (transfusion independent)
	• Creatinine clearance or radioisotope GFR ≥ 70 mL/min OR serum creatinine based on age/gender as follows:

	• 0.4 mg/dL (1 month to < 6 months of age) • 0.5 mg/dL (6 months to < 1 year of age) • 0.6 mg/dL (1 to 2 years of age) • 0.8 mg/dL (2 to < 6 years of age) • 1.0 mg/dL (6 to 10 years of age) • 1.2 mg/dL (10 to 13 years of age) • 1.5 mg/dL (male) or 1.4 mg/dL (female) (13 to < 16 years of age) • 1.7 mg/dL (male) or 1.4 mg/dL (female) (≥ 16 years of age) • Total bilirubin ≤ 1.5 times upper limit of normal (ULN) (≤ 3 times ULN for patients with Gilbert syndrome or hemolytic anemia) • AST or ALT < 3 times ULN • Adequate cardiac function defined as 1 of the following: • Shortening fraction ≥ 27% by ECHO • Ejection fraction ≥ 50% by gated radionuclide study. • Not pregnant or nursing • Patients who agree to stop nursing while on this study are allowed • Negative pregnancy test • Fertile patients must use effective contraception PRIOR CONCURRENT THERAPY: • See Disease Characteristics • No prior treatment for ependymoma other than surgical intervention and corticosteroids
Critères d'exclusion	