Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Essai thérapeutique de difluoromethylornithine (DFMO) en traitement d'entretien chez les enfants atteints de neuroblastome
Protocole ID	NMTRC014
ClinicalTrials.gov ID	NCT02679144
Type(s) de cancer	Pédiatrique divers
Phase	Phase II
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
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Statut	Actif en recrutement
But étude	Difluoromethylornithine (DFMO) will be used in an open label, single agent, multicenter, study for patients with neuroblastoma in remission. In this study subjects will receive 730 Days of oral difluoromethylornithine (DFMO) at a dose of 500 to 1000 mg/m2 BID on each day of study. This study will focus on the use of DFMO in high risk neuroblastoma patients that are in remission as a strategy to prevent recurrence.
Critères d'éligibilité	• All patients must have a pathologically confirmed diagnosis of neuroblastoma, < 30.99 years of age and classified as high risk at the time of diagnosis. Exception: patients who are initially diagnosed as non-high-risk neuroblastoma, but later converted (and/or relapsed) to high risk neuroblastoma are also eligible. • All patients must be in complete remission (CR): • No evidence of residual disease on scan • No evidence of disease metastatic to bone marrow. • Specific Criteria by Stratum: • Stratum 1: All patients must have completed standard upfront therapy that replicates treatment which patients who were enrolled on ANBL0032 received, including: • intensive induction chemotherapy and (if feasible) resection of primary tumor, followed by: consolidation with high-dose chemotherapy with stem cell transplant and radiotherapy, followed by: immunotherapy with Ch14.18/IL-2/GM-CSF (dinutuximab) and retinoic acid;. • All subjects on Stratum 1 must have also met the following criteria: • • A pre-transplant disease status evaluation that met International Neuroblastoma Response Criteria (INRC) for CR (complete response), VGPR (very good partial response), or PR (partial response) for primary site, soft tissue metastases and bone metastases. Patients who meet those criteria must also meet the protocol-specified criteria for bone marrow response prior to transplant as outlined below: No more than 10% tumor involvement (based on total nucleated cellular content) seen on any specimen from a bilateral bone marrow aspirate/biopsy. • Stratum 2: Neuroblastoma that is in first complete remission following standard upfront therapy different from that described for Stratum 1. • Stratum 3: Neuroblastoma that failed to have a response of at least PR following induction chemotherapy and surgical resection of the primary tumor, but that has achieved CR following additional therapy. • Stratum 4: Patients who have achieved a second or subsequent CR following relapse(s). • Pre-enrollment tumor survey: Prior to enrollment on this study, a determination of mandatory disease staging must be performed: • Tumor imaging studies including • Bilateral bone marrow aspirates and biopsy • This disease assessment is required for eligibility and preferably should be done within 2 weeks prior to enrollment, but must be done within a maximum of 4 weeks before enrollment. • Timing from prior therapy:

	• Stratum 1: Enrollment no later than 60 days after completion of upfront therapy, (last dose of cis-retinoic acid) with a maximum of 6 cycles of cis-retinoic acid maintenance therapy. • Stratum 2, 3 and 4: Enrollment no later than 60 days from last dose of the most recent therapy. • Patients must have a Lansky or Karnofsky Performance Scale score of > 50% and patients must have a life expectancy of ≥ 2 months. • All clinical and laboratory studies for organ functions to determine eligibility must be performed within 7 days prior to enrollment unless otherwise indicated below. • Patients must have adequate organ functions at the time of registration: • Hematological: Total absolute phagocyte count ≥1000/µL • Liver: Subjects must have adequate liver function • Renal: Adequate renal function • Females of childbearing potential must have a negative pregnancy test. Patients of childbearing potential must agree to use an effective birth control method. Female patients who are lactating must agree to stop breast-feeding. • Written informed consent in accordance with institutional and FDA (food and drug administration) guidelines must be obtained from all subjects (or patients' legal representative).
Critères d'exclusion	• BSA (Body Surface Area) of <0.25 m2. • Investigational Drugs: Subjects who are currently receiving another investigational drug are excluded from participation. • Anti-cancer Agents: Subjects who are currently receiving other anticancer agents are not eligible. Subjects must have fully recovered from hematological and bone marrow suppression effects of prior chemotherapy. • Infection: Subjects who have an uncontrolled infection are not eligible until the infection is judged to be well controlled in the opinion of the investigator. • Subjects who, in the opinion of the investigator, may not be able to comply with the safety monitoring requirements of the study, or in whom compliance is likely to be suboptimal, should be excluded.