Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	Étude de phase III sur l'utilisation des facteurs de risque basés sur la biologie et la réponse au traitement pour guider la thérapie chez des patients avec un neuroblastome qui n'est pas à risque élevé.
Protocole ID	COG-ANBL-1232
ClinicalTrials.gov ID	NCT02176967
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL CHUL ET CENTRE MERE-ENFANT SOLEIL 2705 boulevard Laurier, Québec, QC, G1V 4G2
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Statut	Actif en recrutement
But étude	This phase III trial studies how well response and biology-based risk factor-guided therapy works in treating younger patients with non-high risk neuroblastoma. Sometimes a tumor may not need treatment until it progresses. In this case, observation may be sufficient. Measuring biomarkers in tumor cells may help plan when effective treatment is necessary and what the best treatment is. Response and biology-based risk factor-guided therapy may be effective in treating patients with non-high risk neuroblastoma and may help to avoid some of the risks and side effects related to standard treatment.
Critères d'éligibilité	• Patients must be: • < 12 months (< 365 days) of age at diagnosis with INRG stage L1; or • < 18 months (< 547 days) of age at diagnosis with INRG stage L2 or stage Ms neuroblastoma/ganglioneuroblastoma • Enrollment on ANBL00B1 is required for all newly diagnosed patients • Patients must have newly diagnosed v-myc avian myelocytomatosis viral oncogene neuroblastoma derived homolog (MYCN) non-amplified neuroblastoma (International Classification of Diseases for Oncology [ICD-O] morphology 9500/3) or MYCN non-amplified ganglioneuroblastoma verified by histology • Patients must meet the specified criteria for one of the treatment groups defined below; genomic features include MYCN gene amplification, segmental chromosome aberrations (somatic copy number loss at 1p, 3p, 4p, or 11q or somatic copy number gain at 1q, 2p, or 17q) and deoxyribonucleic acid (DNA) index • "Favorable" genomic features are defined by one or more whole-chromosome gains or hyperdiploid tumor (DNA index > 1) in the absence of segmental chromosome aberrations as defined above • "Unfavorable" genomic features are defined by the presence of any segmental chromosome aberration (somatic copy number loss at 1p, 3p, 4p, or 11q or somatic copy number gain at 1q, 2p, or 17q) or diploid tumor (DNA index = 1); this includes copy neutral loss of heterozygosity (LOH) • Only patients with MYCN non-amplified tumors are eligible for this study • Group A: patients < 12 months (< 365 days) of age with newly diagnosed INRG stage L1 neuroblastoma/ganglioneuroblastoma who meet the following criteria: • Greatest tumor diameter < 5 cm of adrenal or non-adrenal origin • Patients with non-adrenal primaries are eligible, but must have positive uptake on metaiodobenzylguanidine (MIBG) scan or elevated catecholamine metabolites (urine or serum) to support the diagnosis of neuroblastoma • No prior tumor resection or biopsy

	• Group A will be further split into two subsets, which are mutually exclusive, for statistical purposes • Group A1: • > 6 months and < 12 months of age with an adrenal primary tumor < 5 cm in greatest diameter OR • Patients less than 6 months of age with an adrenal primary tumor > 3.1 and < 5 cm in greatest diameter OR • < 12 months of age with a non-adrenal primary site < 5 cm in greatest diameter • Group A2: =< 6 months of age with an adrenal primary site and tumor =< 3.1 cm in greatest diameter. • Group B: patients < 18 months (< 547 days) of age with newly diagnosed INRG stage L2 neuroblastoma/ganglioneuroblastoma who meet the following criteria: • No life threatening symptoms or no impending neurologic or other organ function compromise (e.g. epidural or intraspinal tumors with existing or impending neurologic impairment, periorbital or calvarial-based lesions with existing or impending cranial nerve impairment, anatomic or mechanical compromise of critical organ function by tumor [abdominal compartment syndrome, urinary obstruction, etc.]) • No prior tumor resection, tumor biopsy ONLY • Only patients with both favorable histology and favorable genomic features will remain on study as part of Group B; the institution will be notified of histologic and genomic results within 3 weeks of specimen submission on ANBL00B1 • Group C: patients < 18 months (< 547 days) of age with newly diagnosed INRG stage Ms neuroblastoma/ganglioneuroblastoma • No prior radiotherapy or chemotherapy, with the exception of dexamethasone, which is allowed • All patients and/or their parents or legal guardians must sign a written informed consent • All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met
Critères d'exclusion	• Patients with MYCN amplified tumors are not eligible • Group B and C patients who do not enroll on ANBL1232 within 4 weeks of definitive diagnostic procedure • Group A and C patients, not required to undergo tumor biopsy, who do not enroll on ANBL1232 within 4 weeks of confirmatory imaging study