Essai Clinique

Généré le 24 avr. 2024 à partir de

Titre	Randomized Controlled Trial of Olanzapine for the Control of Chemotherapy-induced Vomiting in Children Receiving Chemotherapy for Hematopoietic Stem Cell Transplant Conditioning
Protocole ID	1000053716
ClinicalTrials.gov ID	NCT03118986
Type(s) de cancer	Contrôle des symptômes
Phase	Phase II
Type étude	Support
Médicament	Olanzapine
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	
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But étude	Chemotherapy-induced nausea and vomiting (CINV) are among the most bothersome symptoms during cancer treatment according to children and their parents. Most children receiving hematopoietic stem cell transplant (HSCT) conditioning experience CINV despite receiving antiemetic prophylaxis. Olanzapine improves CINV control in adult cancer patients, has a track record of safe use in children with psychiatric illness, does not interact with chemotherapy and is inexpensive. We hypothesize that the addition of olanzapine to standard antiemetics will improve chemotherapy-induced vomiting (CIV) control in children receiving chemotherapy for HSCT conditioning.
Critères d'éligibilité	• Planned autologous or allogeneic HSCT with a conditioning regimen that includes cyclophosphamide ≥ 1 g/m^2/day (≥ 33 mg/kg/day) or highly emetogenic chemotherapy (HEC) • Body weight of at least 12.5 kg • 2.5 to 18 years of age. Note that the minimum body weight requirement corresponds to approximately a 2.5 year old. • A baseline ECG within the month prior to the study drug administration without known clinically significant abnormalities including pathologic prolongation of QTC. • Samples for all laboratory tests will be obtained within one week prior to administration of the first dose of HSCT conditioning: • Plasma creatinine within 1.5 times the upper limit of normal for age. • Amylase within age-appropriate limits • Plasma conjugated bilirubin within ≤ 3x upper limit of normal for age unless attributable to Gilbert's Syndrome • ALT ≤ 5x upper limit of normal for age • A plan for scheduled, round-the-clock receipt of ondansetron, granisetron or palonosetron for antiemetic prophylaxis during administration of HSCT conditioning. • Negative pregnancy test if female of childbearing potential • Patients of childbearing potential must consent to use adequate contraception (males and females) or agree to practice abstinence • Parent or child able to speak a language in which the modified Pediatric Adverse Event Rating Scale (PAERS) is available • Optional: Child participants in the optional assessment of nausea severity must be 4 to 18 years of age. Child and a parent/guardian must be English, Spanish or French-speaking. The PeNAT is validated in English-speaking children 4 to 18 years old with an English-speaking parent/guardian and has been translated into Spanish and French. The MAT is available in English, Spanish and French.

Critères d'exclusion	• CNS malignancy, either primary CNS tumor or CNS metastases. A history of CNS leukemia, in remission at study entry, is allowed. • Pre-existing seizure disorder; known cardiac arrhythmias; known clinically significant ECG abnormalities at baseline including QTc prolongation; uncontrolled diabetes mellitus; history of neuroleptic malignant syndrome; known hypersensitivity or allergy to olanzapine. • Treatment within 14 days prior to the first day of study drug administration with olanzapine or other anti-psychotic agents (e.g. risperidone, quetiapine, aripiprazole, clozapine, butyrophenone) including those used to control CINV (e.g. chlorpromazine, prochlorperazine, promethazine) • Scheduled administration (i.e. not PRN) of antiemetics other than dexamethasone and ondansetron, granisetron or palonosetron is not permitted. Scopolamine patches, aprepitant, fosaprepitant, phenothiazines (e.g. chlorpromazine, prochlorperazine), acupressure or acupuncture are not permitted during the acute and delayed phases. Methylprednisolone and hydrocortisone are permitted during the acute and delayed phases for prevention or treatment of reaction (e.g. thymoglobulin, alemtuzumab, blood products) and during delayed phase for GVHD prophylaxis. Administration of olanzapine other than ordered as per study procedures is not permitted. However, other antiemetics may be administered as needed (PRN) for treatment of breakthrough CINV. For patients receiving busulfan, scheduled administration of benzodiazepines such as lorazepam for seizure prophylaxis is permitted on the days that busulfan is given and for 24 hours after. • Receipt of cranial boost radiation within 14 days of the first day of HSCT conditioning. • Planned co-administration of citalopram, amifostine, medications known to alter the metabolism of olanzapine (e.g. ciprofloxacin, valproic acid) • Previous participation in this study. • Participants in the optional assessment of nausea severity must be free of cognitive, hearing or visual impairment that preclude completion of the PeNAT.