Essai Clinique

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Titre	Essai clinique randomisé de phase 3 évaluant l'addition de Ganitumab (AMG 479, NSC# 750008), un anticorps monoclonal dirigé contre IGF-1R, à une chimiothérapie comportant plusieurs agents pour les patients ayant été nouvellement diagnostiqués avec un sarcome d'Ewing métastasique.
Protocole ID	COG-AEWS1221
ClinicalTrials.gov ID	NCT02306161
Type(s) de cancer	Pédiatrique divers
Phase	Phase III
Institution	CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE
Ville	Montréal
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Statut	Fermé
But étude	This randomized phase III trial studies how well combination chemotherapy with or without ganitumab works in treating patients with newly diagnosed Ewing sarcoma that has spread to other parts of the body. Monoclonal antibodies, such as ganitumab, may block tumor growth in different ways by targeting certain cells. Drugs used in chemotherapy, such as vincristine sulfate, doxorubicin hydrochloride, cyclophosphamide, ifosfamide, and etoposide, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether combination chemotherapy is more effective with or without ganitumab in treating patients with newly diagnosed Ewing sarcoma.
Critères d'éligibilité	• Patients with histologic diagnosis (by institutional pathologist) of newly diagnosed Ewing sarcoma or peripheral primitive neuroectodermal tumor (PNET) arising from bone or soft tissue and with metastatic disease involving lung, bone, bone marrow, or other metastatic site • For the purpose of this study metastatic disease is defined as one or more of the following: • Lesions which are discontinuous from the primary tumor, are not regional lymph nodes, and do not share a bone or body cavity with the primary tumor; skip lesions in the same bone as the primary tumor do not constitute metastatic disease; skip lesions in an adjacent bone are considered bone metastases; if there is any doubt whether lesions are metastatic, a biopsy of those lesions should be performed • Contralateral pleural effusion and/or contralateral pleural nodules • Distant lymph node involvement • Patients with pulmonary nodules are considered to have metastatic disease if the patient has: • Solitary nodule >= 0.5 cm or multiple nodules of >= 0.3 cm unless lesion is biopsied and negative for tumor • Patients with solitary nodule < 0.5 cm or multiple nodules < 0.3 cm are not considered to have lung metastasis unless biopsy documents tumor • Bone marrow metastatic disease is based on morphologic evidence of Ewing sarcoma based on hematoxylin and eosin (H&E) stains; in the absence of morphologic evidence of marrow involvement on H&E, patients with bone marrow involvement detected ONLY by flow cytometry, reverse-transcriptase (RT)-polymerase chain reaction (PCR), fluorescence in situ hybridization (FISH), or immunohistochemistry will NOT be considered to have clinical bone marrow involvement for the purposes of this study • This study requires bilateral bone marrow biopsies at study entry; the suggested approach for patients with large pelvic tumors in which a posterior iliac crest bone marrow biopsy would track through the tumor is to instead undergo 2 marrow biopsies on the contralateral side (either 2 posterior biopsies or one posterior and one anterior biopsy) • Bone metastasis: This study utilizes whole body FDG-PET scans to screen patients for bone metastases; areas suspicious for bone metastasis based on FDG-PET scans require confirmatory anatomic imaging with either MRI or computed tomography (CT) (whole body

	FDG-PET/CT or FDG-PET/magnetic resonance [MR] scan acceptable); whole body technetium bone scans may be performed at the discretion of the investigator and are not required; for patients without other sites of metastatic disease whose sole metastatic site to qualify for study entry is a single area suspicious for bone metastasis identified by FDG-PET, confirmatory biopsy or anatomic imaging evidence of an associated soft tissue mass at that site is required for study entry • Patients must have adequate tumor tissue to meet the minimum requirement for submission • Enrolling institutions are reminded that submission of pre-treatment serum, tumor tissue and whole blood is required • Patients should only have had a biopsy of the primary tumor without an attempt at complete or partial resection; patients will still be eligible if excision was attempted or accomplished as long as adequate anatomic imaging (MRI for most primary tumor sites) was obtained prior to surgery • Creatinine clearance or radioisotope glomerular filtration rate (GFR) >= 70 mL/min/1.73 m^2 or a serum creatinine based on age/gender as follows: • Age < 6 months: Maximum serum creatinine (mg/dL): 0.4 for males and females • Age 6 months to < 1 year: Maximum serum creatinine (mg/dL): 0.5 for males and females • Age 1 to < 2 years: Maximum serum creatinine (mg/dL): 0.6 for males and females • Age 2 to < 6 years: Maximum serum creatinine (mg/dL): 0.8 for males and females • Age 6 to < 10 years: Maximum serum creatinine (mg/dL): 1 for males and females • Age 10 to < 13 years: Maximum serum creatinine (mg/dL): 1.2 for males and females • Age 13 to < 16 years: Maximum serum creatinine (mg/dL): 1.5 for males and 1.4 for females • Age >= 16 years: Maximum serum creatinine (mg/dL): 1.7 for males and 1.4 for females • Total bilirubin =< 1.5 x upper limit of normal (ULN) for age, and • Serum glutamate pyruvate transaminase (SGPT) (alanine aminotransferase [ALT]) < 3 x upper limit of normal (ULN) for age (except for patients with liver metastasis who may enroll if ALT < 5 times ULN for age) • Shortening fraction of >= 27% or • Ejection fraction of >= 50% • Patients must have a normal blood sugar level for age to participate; if an initial random draw (ie. non-fasting) blood glucose value is out of range, it is acceptable to repeat this test as a fasting draw • 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 regional node involvement as their only site of disease beyond the primary tumor will not be eligible • Patients whose primary tumors arise in the intra-dural soft tissue (eg. brain and spinal cord) are not eligible • Patients who have received prior chemotherapy or radiation therapy are not eligible • Female patients of childbearing potential are not eligible unless a negative pregnancy test result has been obtained; lactating females are not eligible unless they have agreed not to breastfeed their infants for the duration of protocol therapy; sexually active patients of reproductive potential are not eligible unless they have agreed to use an effective contraceptive method for the duration of protocol therapy • Patients with known pre-existing diabetes mellitus will be excluded from study • Patients receiving chronic pharmacologic doses of corticosteroids are not eligible; for the purposes of eligibility, chronic exposure is defined as anticipated exposure of > 3 weeks, including the sum of both pre-enrollment and anticipated post-enrollment dosing; patients on acute corticosteroid therapy (=< 3 weeks of total planned exposure) must still meet the normal blood glucose requirement; patients receiving chronic inhaled corticosteroids or chronic physiologic replacement doses of corticosteroids are eligible