Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Études randomisées des phases II et III du traitement individualisé pour un carcinome du rhinopharynx, selon le marqueur biologique de l'acide désoxyribonucléique (ADN) du virus d'Epstein-Barr (VEB)
Protocole ID	RTOG 1305
ClinicalTrials.gov ID	NCT02135042
Type(s) de cancer	ORL
Phase	Phase II
Type étude	Traitement
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
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Statut	Actif en recrutement
But étude	There are two study questions we are asking in this randomized phase II/III trial based on a blood biomarker, Epstein Barr virus (EBV) deoxyribonucleic acid (DNA) for locoregionally advanced non-metastatic nasopharyngeal cancer. All patients will first undergo standard concurrent chemotherapy and radiation therapy. When this standard treatment is completed, if there is no detectable EBV DNA in their plasma, then patients are randomized to either standard adjuvant cisplatin and fluorouracil chemotherapy or observation. If there is still detectable levels of plasma EBV DNA, patients will be randomized to standard cisplatin and fluorouracil chemotherapy versus gemcitabine and paclitaxel. Radiation therapy uses high energy x rays to kill tumor cells. Drugs used in chemotherapy, such as cisplatin, fluorouracil, gemcitabine hydrochloride, and paclitaxel 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 giving cisplatin and fluorouracil is more effective than gemcitabine hydrochloride and paclitaxel after radiation therapy in treating patients with nasopharyngeal cancer.
Critères d'éligibilité	• Biopsy proven (from primary lesion and/or lymph nodes) diagnosis of cancer of the nasopharynx • Patients must have detectable pretreatment plasma EBV DNA, determined by the central lab prior to Step 2 registration • Stage II-IVB disease (American Joint Committee on Cancer [AJCC], 7th edition [ed.]) with no evidence of distant metastasis, based upon the following minimum diagnostic workup: • History/physical examination by a Medical Oncologist or Clinical Oncologist or Radiation Oncologist or Ear, Nose, Throat specialist (ENT), which must include an endoscopic evaluation, a complete list of current medications, and assessment of weight and weight loss in the past 6 months within 21 days prior to registration • Evaluation of tumor extent with magnetic resonance imaging (MRI) of the nasopharynx and neck within 28 days prior to registration; if MRI is medically contraindicated, obtain computed tomography (CT) scan with =< 3 mm contiguous slices with contrast and bone windows (to evaluate base of skull involvement); Note: If a treatment planning CT scan is used, it must be with =< 3 mm contiguous slices with contrast and be read by a radiologist • To rule out distant metastasis, patients must undergo the following imaging within 28 days prior to registration: • A CT scan with contrast of the chest, abdomen, and/or pelvis or a total body positron emission tomography (PET)/CT scan (non-contrast PET/CT is acceptable) • A bone scan only when there is suspicion of bone metastases (a PET/CT scan can substitute for the bone scan) • Zubrod performance status 0-1 within 21 days prior to registration

	• Absolute neutrophil count (ANC) >= 1,500 cells/mm^3 • Platelets >= 100,000 cells/mm^3 • Hemoglobin >= 8.0 g/dl (Note: the use of transfusion or other intervention to achieve hemoglobin [Hgb] >= 8.0 g/dl is acceptable) • Total bilirubin =< 1.5 x institutional upper limit of normal (ULN) • Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) =< 1.5 x institutional ULN • Alkaline phosphatase =< 1.5 x institutional ULN • Serum creatinine =< 1.5 mg/dl or calculated creatinine clearance (CC) >= 50 ml/min determined by 24-hour urine collection or estimated by Cockcroft-Gault formula • Negative serum pregnancy test within 14 days prior to registration for women of childbearing potential • Women of childbearing potential and male participants who are sexually active must agree to use a medically effective means of birth control throughout protocol treatment • Patient must provide study specific informed consent prior to study entry, including the mandatory pre-treatment plasma EBV DNA assay
Critères d'exclusion	• Prior invasive malignancy (except node negative, non-melanomatous skin cancer) unless disease free for a minimum of 1095 days (3 years) (for example, carcinoma in situ of the breast, oral cavity, or cervix are all permissible) • Prior systemic chemotherapy for the study cancer; note that prior chemotherapy for a different cancer is allowable; however, at least 6-weeks recovery is necessary if the last regimen included nitrosourea or mitomycin • Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields • Patients with hearing loss assessed to be primarily sensorineural in nature, requiring a hearing aid, or intervention (i.e. interfering in a clinically significant way with activities of daily living); a conductive hearing loss from tumor-related otitis media is allowed • >= Grade 2 peripheral sensory neuropathy (CTCAE, v. 4.0) • Severe, active co-morbidity, defined as follows: • Major medical or psychiatric illness, which in the investigator's opinion would interfere with the completion of therapy and follow up or with full understanding of the risks and potential complications of the therapy • Unstable angina and/or uncontrolled congestive heart failure • Myocardial infarction within the last 6 months • Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration; note that patients switched from IV antibiotics and currently on oral antibiotics whose infection is assessed to be adequately treated or controlled are eligible • Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy within 30 days prior to registration • Acquired immune deficiency syndrome (AIDS) based upon current Centers for Disease Control and Prevention (CDC) definition; note, however, that human immunodeficiency virus (HIV) testing is not required for entry into this protocol • Pregnancy or women of childbearing potential and men who are sexually active and not willing/able to use medically acceptable forms of contraception • Prior allergic reaction to the study drug(s) involved in this protocol • Patients with undetectable pre-treatment plasma EBV DNA