Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	ROMAN : Réduction de la mucosite buccale avec le Avasopasem Manganese (GC4419) - Étude de phase 3 chez les patients recevant de la chimioradiothérapie dans le traitement du cancer de la tête et du cou localement avancé et non métastatique
Protocole ID	GTI-4419-301
ClinicalTrials.gov ID	NCT03689712
Type(s) de cancer	ORL
Phase	Phase III
Stade	Localement avancé
Type étude	Support
Médicament	Superoxide Dismutase Mimetic GC4419
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dr Nader Khaouam
Coordonnateur	Véronique Tran 514-252-3400 poste 3227
Statut	Fermé
But étude	The purpose of the phase 3, clinical study is to determine if GC4419 administered prior to intensity-modulated radiation therapy (IMRT) reduces the severity of radiation induced oral mucositis in patients who have been diagnosed with locally advanced, non-metastatic squamous cell carcinoma of the head and neck.
Critères d'éligibilité	• squamous cell carcinoma of the head and neck • treatment plan to receive IMRT delivered as single daily fractions of 2.0 to 2.2 Gy with a cumulative radiation dose of 60-72 Gy • Treatment plan to receive standard cisplatin monotherapy • Age 18 years or older • Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 • Adequate hematologic, renal and liver function • Negative serum pregnancy test • Use of effective contraception
Critères d'exclusion	• Tumor of the lips, larynx, hypopharynx, nasopharynx, sinuses, or salivary glands • Metastatic disease • Prior radiotherapy to the region of the study cancer or adjacent anatomical • Prior induction chemotherapy • Receiving any approved or investigational anti-cancer agent other than those provided for in this study • Concurrent participation in another interventional clinical study • Inability to eat soft solid food at baseline • Malignant tumors other than HNC within the last 5 years • Active infectious disease excluding oral candidiasis • Presence of oral mucositis at baseline • Known history of HIV or active hepatitis B/C

- Female patients who are pregnant or breastfeeding
- Known allergies or intolerance to cisplatin and similar platinum-containing compounds
- Requirement for concurrent treatment with nitrates or other drugs that may create a risk for a precipitous decrease in blood pressure