



Essai Clinique

Généré le 03 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	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dr Phuc-Félix Nguyen Tân
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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