Essai Clinique

Généré le 28 janv. 2022 à partir de

Titre	Effet local du bisphosphonate sur les taux de récidive des tumeurs à cellules géantes aux épiphyses (extrémités) de l'os
Protocole ID	28229
ClinicalTrials.gov ID	NCT03295981
Type(s) de cancer	Sarcome
Phase	Phase III
Type étude	Traitement
Médicament	Acide Zolédronique
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL HOPITAL GENERAL DE MONTREAL 1650 Avenue Cedar, Montréal, QC, H3G 1A4
Ville	
Investigateur principal	Dr Robert Turcotte
Coordonnateur	Mireille Dessureault 514-934-1934 poste 43022
Statut	Actif en recrutement
But étude	The purpose of the clinical study is to investigate whether the local delivery of bisphosphonate as a surgical adjuvant can decrease the chance of a giant cell tumor of bone coming back to the same location. The hypothesis is that the local administration of bisphosphonate will decrease the rate of the tumor returning compared to traditional aggressive surgical removal of the tumor.
Critères d'éligibilité	• Primary benign GCT of bone • Lesion located in an extremity • Lesion amenable to reconstruction (intralesional curettage) defined as having at least one intact column of bone after removal • No previous systemic bisphosphonate or denosumab therapy • Serum creatinine level less than 3.5 mg/dL • Corrected total serum calcium level of 8.0 mg/dL or greater
Critères d'exclusion	• Recurrent GCT of bone • Non-extremity location • Lesion too extensive for intralesional treatment, either due to bone loss, joint invasion, or large soft tissue component • Children and pregnancy • Previous systemic bisphosphonate or denosumab therapy • Hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation • Patients with severe renal impairment (drug excreted by the kidney) • Patients with hypocalcaemia