Essai Clinique

Généré le 11 mai 2025 à partir de

Titre	Étude de suivi à long terme de phase 4 visant à définir le profil d'innocuité du dichlorure de radium 223
Protocole ID	16996
ClinicalTrials.gov ID	NCT02312960
Type(s) de cancer	Autre
Phase	Phase IV
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
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Statut	Fermé
But étude	This long-term follow up study will enroll subjects who will be transferred from selected interventional, company sponsored trials with radium-223 dichloride (feeder trials).The primary objectives are to define the long term safety profile of radium-223 dichloride (for up to 7 years after the last dose of radium-223 dichloride); to assess the incidence of leukemia, myelodysplastic syndrome, aplastic anemia, and primary bone cancer or any other new primary malignancy; to assess the incidence of bone fractures and bone associated events (e.g., osteoporosis); and, in subjects who receive cytotoxic chemotherapy, to assess the incidence of febrile neutropenia and hemorrhage during their chemotherapy treatment and for up to 6 months thereafter at a frequency based on local clinical practice.
Critères d'éligibilité	• Subject was previously enrolled in a selected company sponsored feeder trial, and has received at least 1 dose of radium 223 dichloride or placebo in the feeder trial
Critères d'exclusion	• Not applicable to this follow up study