Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	Étude de phase III à répartition aléatoire et à double insu comparant l'immunothérapie adjuvante par le nivolumab et un placebo après la résection complète d'un mélanome de stade 2B/C
Protocole ID	CA209-76K
ClinicalTrials.gov ID	NCT04099251
Type(s) de cancer	Mélanome
Phase	Phase III
Type étude	Traitement
Médicament	Nivolumab
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
Investigateur principal	Dr Robert Hanel
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Statut	Fermé
But étude	The purpose of this study is to determine the effectiveness of nivolumab adjuvant immunotherapy compared to placebo in adults and pediatric participants after complete resection of Stage IIB/C melanoma with no evidence of disease (NED) who are at high risk for recurrence.
Critères d'éligibilité	• Had a negative sentinel lymph node biopsy • Participant has not been previously treated for melanoma • ECOG 0 or 1 • Participants must have been diagnosed with histologically confirmed, Resected, Stage IIB/C cutaneous melanoma
Critères d'exclusion	• History of ocular or mucosal melanoma. • Pregnant or nursing women • Participants with active known or suspected autoimmune disease • Known history of allergy or hypersensitivity to study drug components • Prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, anti-CTLA-4 antibody, or agents that target IL-2 pathways, T-cell stimulators, or checkpoint pathways • Other protocol defined inclusion/exclusion criteria could apply.