Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	Étude internationale de phase III multicentrique, contrôlée par placebo, à double insu et à répartition aléatoire portant sur le durvalumab à la suite d'une radiothérapie stéréotaxique corporelle pour le traitement des patients atteints d'un cancer du poumon non à petites cellules de stade I/II non réséqué sans envahissement ganglionnaire lymphatique
Protocole ID	PACIFIC-4/RTOG-351
ClinicalTrials.gov ID	NCT03833154
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Type étude	Traitement
Médicament	Radiothérapie stéréotaxique suivi de Durvalumab vs placebo
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dre Thi Trinh Thuc Vu
Coordonnateur	Diane Trudel 514-890-8000 poste 11181
Statut	Actif en recrutement
But étude	This is a Phase III, randomized, placebo-controlled, double-blind, multi-center study assessing the efficacy and safety of durvalumab versus placebo following SoC SBRT in patients with unresected clinical Stage I/II lymph node-negative (T1 to T3N0M0) NSCLC.
Critères d'éligibilité	• Age ≥18 years • Histologically or cytologically documented Stage I to II NSCLC, with clinical Stage I/II lymph node-negative (T1 to T3N0M0) disease and planned to receive definitive treatment with SBRT. Patients may be medically inoperable or are medically operable and refusing surgery or choosing to have SBRT (Stereotactic Body Radiation Therapy) as definitive therapy • Completion of SoC SBRT as definitive treatment prior to randomization • World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) PS of 0, 1, or 2 • Life expectancy of at least 12 weeks • Body weight >30 kg • Tumor sample required • Adequate organ and marrow function required • Patients with central or peripheral lesions are eligible • Staging studies must be done within 8 weeks before randomization
Critères d'exclusion	• Mixed small cell and non-small cell cancer histology • History of allogeneic organ transplantation • History of another primary malignancy with exceptions • History of active primary immunodeficiency • Any unresolved toxicity National Cancer Institute (NCI) CTCAE Grade ≥2 from SBRT (Stereotactic Body Radiation Therapy)