Essai Clinique

Généré le 17 mai 2025 à partir de

Titre	Étude prospective non interventionnelle chez des patients atteints d'un cancer avec fusion du gène TRK localement avancé ou métastatique traités par le larotrectinib
Protocole ID	20324
ClinicalTrials.gov ID	NCT04142437
Type(s) de cancer	Tumeurs solides
Phase	Autres
Type étude	Autre
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL CHUL ET CENTRE MERE-ENFANT SOLEIL 2705 boulevard Laurier, Québec, QC, G1V 4G2
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Statut	Actif en recrutement
But étude	In this observational study researcher want to learn more about the effectiveness of drug VITRAKVI (generic name: larotrectinib) and how well the drug is tolerated during routine use in patients with TRK fusion cancer which is locally advanced or spread from the place where it started to other places in the body. TRK fusion cancer is a term used to describe a variety of common and rare cancers that are caused by a change to the NTRK (Neurotrophic Tyrosine Kinase) gene called a fusion. During this fusion, an NTRK gene joins together, or fuses, with a different gene. This joining results in the activation of certain proteins (TRK fusion proteins), which can cause cancer cells to multiply and form a tumor. VITRAKVI is an approved drug that blocks the action of the NTRK gene fusion. This study will enroll adult and paediatric patients suffering from a solid tumor with NTRK gene fusion for whom the decision to treat their disease with VITRAKVI has been made by their treating physicians. During the study, patients' medical information such as treatment information with VITRAKVI, other medication or treatments, changes in disease status and other health signs and symptoms will be collected within the normal medical care by the treating doctor. Participants will be observed over a period from 24 to 60 months.
Critères d'éligibilité	• Adult and pediatric (from birth to 18 year old) patients • Patients with locally advanced or metastatic solid tumor harboring an NTRK gene fusion. NTRK (NTRK1, NTRK2, and NTRK3) gene fusions will be identified locally. Acceptable methods of detection of NTRK gene fusion include NGS, fluorescence in situ hybridization (FISH), reverse-transcription polymerase chain reaction (rt-PCR) or any other genomic testing able to detect NTRK gene fusion. If a pan-TRK IHC method is used, this result needs to be accompanied with the results using one of the other methods noted above. • Life expectancy of at least 3 months based on clinical judgement • Decision to treat with larotrectinib made by the treating physician prior to study enrollment • Signed informed consent form • For patients under legal age, signed assent by the patient (where applicable) and parental/legal guardian signed informed consent is required
Critères d'exclusion	• Any contraindications as listed in the local approved product information • Pregnancy • Participation in an investigational program with interventions outside of routine clinical practice • Prior treatment with larotrectinib or other kinase inhibitor with TRK inhibition • Patients with NTRK gene amplification or NTRK point mutation