Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	A Phase IV, Real World Observational Study On The Use Of Akynzeo® (Netupitant/Palonosetron) For The Prevention Of Nausea and Vomiting in Oncology Patients Receiving Highly Emetogenic Chemotherapy (HEC) Over Multiple Cycles.
Protocole ID	CAN-PRO-NEPA-001 (EVOLVE)
ClinicalTrials.gov ID	NCT03649230
Type(s) de cancer	Autre
Phase	Phase IV
Type étude	Support
Médicament	Netupitant/Palonosetron
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	Greenfield Park
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Statut	Fermé
But étude	This Canadian, multi-centre, prospective, observational real-world study is designed to collect patient-reported outcome data on the use of Akynzeo® (netupitant/palonosetron) for the prevention of nausea and vomiting in oncology patients receiving highly emetogenic chemotherapy (HEC).
Critères d'éligibilité	• Patient scheduled to receive a highly emetogenic chemotherapy (HEC). • Patient scheduled to receive antiemetic prevention with Akynzeo® according to the approved Canadian Product Monograph as deemed medically necessary by the participating physician independently from this study. • Age ≥ 18 years. • Women of childbearing potential must use effective contraception during therapy and up to one month after treatment with Akynzeo®. • Patient (and/or patient's authorized legal representative) should understand the nature of the study and provide written informed consent prior to or at the screening visit. • Patient is able and willing to comply with the study protocol for the entire length of the study and will follow all study requirements, procedures and complete all visits as required. • Patient is participating in another clinical trial where antiemetic treatment is not pre-specified by the study protocol.
Critères d'exclusion	• Women of child bearing potential who are pregnant, planning on becoming pregnant or breast feeding. • Hypersensitivity to active substances, excipients or other ingredients of Akynzeo®. • Concomitant use of pimozide, terfenadine, astemizole, or cisapride. • Patient currently enrolled in another clinical trial where antiemetic treatment is pre-specified by the study protocol.