Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Randomized Control Trial to Compare Doxycycline to Isotretinoin for the Treatment of Acneiform Eruptions in Cancer Patients on Tyrosine Kinase Inhibitors
Protocole ID	2021-2635
ClinicalTrials.gov ID	NCT04864717
Type(s) de cancer	Contrôle des symptômes
Phase	Phase IV
Type étude	Clinique
Médicament	Doxycycline versus Isotretinoin
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Kevin Pehr
Coordonnateur	
Statut	Actif en recrutement
But étude	Tyrosine Kinase inhibitors (TKIs) have become standard of care in patients with EGFR mutations in non-small cell lung cancer and other EGFR-mutated cancers. However, TKIs are well-known to cause cutaneous adverse events, including acneiform eruptions. Moderate to severe acneiform eruptions are often associated with severe pruritus and pain. Current treatment recommendations rely on expert consensus. Moderate and severe reactions requiring systemic therapy, usually tetracycline antibiotics or isotretinoin. No randomized trial has compared the relative effectiveness of tetracyclines versus isotretinoin. The objective of this unblinded, randomized trial is to compare tetracyclines to isotretinoin for treatment of moderate to severe acneiform eruptions in cancer patients on tyrosine kinase inhibitors. The primary aim of this clinical trial is to elucidate which systemic treatment is more effective in clearing acneiform eruptions caused by TKIs. The results of this study will add to the literature in this field and will aid in developing evidence based clinical guidelines.
Critères d'éligibilité	• Participant must be ≥18 years of age, able to understand the study procedures, and agrees to participate in the study by providing written informed consent • Participant has histologically- or pathologically-confirmed cancer with a known sensitizing EGFR mutation. • Participants must have started EGFR-TKI treatment, and subsequently had an acneiform eruption rated moderate or severe per the Leeds scale. • Participant has an Eastern Cooperative Oncology Group (ECOG) performance status score of 0-2. • Participant has a life expectancy of at least 3 months. • Premenopausal participants must use highly effective method of contraception. Female participants are neither pregnant nor breastfeeding

Critères d'exclusion	• Absolute contraindications: pregnancy, breastfeeding, drug allergy
	• Relative contraindications:
	  • moderate to severe hypercholesterolemia (total cholesterol >7.8 mmol/L)
	  • hypertriglyceridemia (TG >2.55 mmol/L)
	  • significant hepatic dysfunction (AST > 55IU/L, ALT > 94 IU/L)
	  • suicidal ideation, pseudotumor cerebri
	  • refractory nausea or vomiting
	  • GI pathology that would prevent absorption of oral therapy.