Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	A Randomized, Open-Label, Phase 3 Trial of Tisotumab Vedotin vs Investigator's Choice Chemotherapy in Second- or Third-Line Recurrent or Metastatic Cervical Cancer
Protocole ID	innovaTV 301 (SGNTV-003)
ClinicalTrials.gov ID	NCT04697628
Type(s) de cancer	Col
Phase	Phase III
Type étude	Clinique
Médicament	Tisotumab védotine versus une chimiothérapie au choix de l'investigateur
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Vanessa Samouëlian
Coordonnateur	France Gauthier 514-890-8000 poste 30921
Statut	Fermé
Date d'activation	08-12-2022
But étude	This trial is being done to find out whether tisotumab vedotin works better than chemotherapy to treat cervical cancer. People in this study have cervical cancer that has spread to other parts of the body (metastatic) or has come back after being treated (recurrent).Participants in this trial will be randomly assigned to one of two groups. One group will be treated with tisotumab vedotin. Participants in the other group will get one of five different chemotherapy drugs (topotecan, vinorelbine, gemcitabine, pemetrexed, or irinotecan). Participants and their doctors will know which group they are in. Participants in the chemotherapy group will decide with their study doctor which drug they will take.

Critères d'éligibilité	• Has recurrent or metastatic cervical cancer with squamous cell, adenocarcinoma, or adenosquamous histology, and:
	• Has experienced disease progression during or after treatment with a standard of care systemic chemotherapy doublet, or platinum-based therapy (if eligible), defined as either:
	  • paclitaxel + cisplatin + bevacizumab + anti-PD-(L)1 agent, or
	  • paclitaxel + carboplatin + bevacizumab + anti-PD-(L)1 agent, or
	  • paclitaxel + topotecan/nogitecan + bevacizumab + anti-PD-(L)1 agent
	• Note: In cases where bevacizumab and/or anti-PD-(L)1 agent is not a standard of care therapy or the participant was ineligible for such treatment according to local standards, prior treatment with bevacizumab and/or anti-PD-(L)1 agent is not required.
	• Has received 1 or 2 prior systemic therapy regimens for recurrent and/or metastatic cervical cancer. Chemotherapy administered in the adjuvant or neoadjuvant setting, or in combination with radiation therapy, should not be counted as a systemic therapy regimen. Single agent therapy with an anti-PD(L)1 agent for r/mCC cancer should be counted.
	• Measurable disease according to RECIST v1.1 as assessed by the investigator.
	• Has ECOG performance status of 0 or 1 prior to randomization.
	• Has life expectancy of at least 3 months.

Critères d'exclusion	• Has primary neuroendocrine, lymphoid, sarcomatoid, or other histologies not mentioned as part of the inclusion criteria above. • Has clinically significant bleeding issues or risks. This includes known past or current coagulation defects leading to an increased risk of bleeding; diffuse alveolar hemorrhage from vasculitis; known bleeding diathesis; ongoing major bleeding; trauma with increased risk of life-threatening bleeding or history of severe head trauma or intracranial surgery within 8 weeks of trial entry. • Has any history of intracerebral arteriovenous malformation, cerebral aneurysm, or stroke (transient ischemic attack >1 month prior to screening is allowed). • Active ocular surface disease or a history of cicatricial conjunctivitis or inflammatory conditions that predispose to cicatrizing conjunctivitis (e.g. Wagner syndrome, atopic keratoconjunctivitis, autoimmune disease affecting the eyes), ocular Stevens-Johnson syndrome or toxic epidermal necrolysis, mucus pemphigoid, and participants with penetrating ocular transplants. Cataracts alone is not an exclusion criterion. • Major surgery within 4 weeks or minor surgery within 7 days prior to the first study treatment administration. • Peripheral neuropathy ≥grade 2. • Any prior treatment with monomethyl auristatin E (MMAE)-containing drugs. There are additional inclusion and exclusion criteria. The study center will determine if criteria for participation are met.