Essai Clinique

Généré le 01 mai 2024 à partir de

Titre	Essai avec répartition aléatoire de phase III sur la durée du traitement anti-PD-1 dans le mélanome métastatique (STOP-GAP)
Protocole ID	ME13
ClinicalTrials.gov ID	NCT02821013
Type(s) de cancer	Mélanome
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
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Statut	Actif en recrutement
But étude	The purpose of this study is to compare the effects on patients with metastatic melanoma of taking a government approved and paid-for PD-1 inhibitor intermittently, with taking the same type of agent continuously. Researchers want to see if the two ways of giving this type of treatment work equally well in extending the life of patients with melanoma, or not.
Critères d'éligibilité	• Histologically confirmed melanoma that is unresectable / metastatic (stage III or stage IV). • Eligible to receive treatment with a government approved and publically-funded PD-1 inhibitor, according to the guidance / indications described in the Product Monograph / Provincial Formulary. • Patients must have evidence of unresectable / metastatic disease, that is considered evaluable by the investigator and can be followed, but measurable disease is not mandatory. • Patients with brain metastases are allowed, provided they are stable according to the following definitions: • Without evidence of progression for at least four weeks prior to randomization and have no evidence of new or enlarging brain metastases. • Treated with surgery and without evidence of progression prior to randomization and have no evidence of new or enlarging brain metastases. • Treated with stereotactic radiosurgery and without evidence of progression prior to randomization and have no evidence of new or enlarging brain metastases. • Patient is able (i.e. sufficiently fluent) and willing to complete the quality of life and health utility questionnaires in either English or French. The baseline assessment must be completed within required timelines, prior to randomization. Inability (lack of comprehension in English or French, or other equivalent reason such as cognitive issues or lack of competency) to complete the questionnaires will not make the patient ineligible for the study. However, ability but unwillingness to complete the questionnaires will make the patient ineligible. • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrollment in the trial to document their willingness to participate. • Patients must be accessible for treatment and follow-up. Investigators must assure themselves the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up. • Patients must be randomized prior to the start of, or within 16 weeks from, the initiation of PD-1

	inhibitor treatment. For patients who are being randomized before the start of treatment, the PD-1 inhibitor should be started within 5 working days after randomization.
Critères d'exclusion	• Patients not willing to stop anti-PD-1 therapy, if randomized to the intermittent arm. • Patients with any contraindications to PD-1 inhibitors, as described in the Product Monograph or Provincial Formulary, and/or not eligible to receive anti-PD-1 therapy.