# Essai Clinique

Généré le 02 mai 2024 à partir de

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| Titre | Phase I Trial of Camu Camu Prebiotic and Immune Checkpoint Inhibition in Patients With Non-Small Cell Lung Cancer and Melanoma |
| Protocole ID | BR-2021-CamuCamu |
| ClinicalTrials.gov ID | NCT05303493 |
| Type(s) de cancer | Mélanome<br>Poumon non à petites cellules |
| Phase | Phase I |
| Type étude | Clinique |
| Institution | CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL |
| Ville | |
| Investigateur principal | Dr Bertrand Routy |
| Coordonnateur | Wiam Belkaid<br>514-890-8000 |
| Statut | Actif en recrutement |
| Date d'activation | 17-08-2022 |
| But étude | Modulating the gut microbiome to improve response to immune-checkpoint inhibitors is an active area of study. Prebiotic substances (compounds which positively shift the gut microbiome) are a reliable and safe method of gut microbiome modulation. Data suggest that the berry Camu Camu (CC), also known as Myrciaria dubia has prebiotic potential to enrich Akkermansia muciniphila, a bacterium shown to alleviate metabolic disorders and improve ICI efficacy in preclinical models. Our primary objective is to assess the safety and tolerability of CC prebiotic in patients with advanced NSCLC and melanoma in combination with standard-of-care ICI. |
| Critères d'éligibilité | • Signed, informed consent;<br>• Age 18 years or older;<br>• One of the following histological-confirmed diagnoses**<br>• No prior anti-PD1 treatment (except for patients in cohort 3)<br>• Evaluable disease as per RECIST 1.1;<br>• ECOG performance status of 0-2;<br>• Ability to ingest capsules;<br>• Patients receiving systemic steroids at physiologic doses are permitted to enroll provided the dose not exceed 10 mg prednisone daily or equivalent;<br>• Negative pregnancy test for women of child-bearing potential; and<br>• Highly effective contraception (any method above 97% success rate) for both male and female subjects throughout the study and for at least 60 days after last treatment administration, if the risk of conception exists<br>  • **Cohort 1:** patients with stage IV or unresectable NSCLC (including squamous cell carcinoma) with PD-L1 expression <50% who are going to be treated with anti-PD-1 in combination with platinum-doublet chemotherapy<br>  • **Cohort 2:** Patients with untreated stage IV or unresectable cutaneous melanoma, acral or mucosal melanoma who are going to be treated with single-agent anti-PD-1 therapy i. Patients with prior treatment with BRAF-targeting agents (BRAF inhibition +/- MEK inhibition) are permitted to enroll ii. Patients with melanoma of unknown primary are permitted to enroll. Diagnosis of melanoma of unknown primary at the discretion of the treating oncologist and sponsor<br>  • **Cohort 3:** Patients with stage IV or unresectable cutaneous melanoma, acral or mucosal melanoma already receiving standard-of-care ICI (either single-agent anti-PD-1 or combination anti-CTLA-4 plus anti-PD-1) at the first sign of progression i.Patients with |

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| | melanoma of unknown primary are permitted to enroll. Diagnosis of melanoma with unknown primary at the discretion of the treating oncologist and PI. |
| Critères d'exclusion | • Pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 120 days after the last dose of trial treatment;<br>• Has a diagnosis of severe immunodeficiency (e.g. transplantation) or receiving systemic steroid therapy (>10mg prednisone daily or equivalent) or any other form of active immunosuppressive therapy at the discretion of the sponsor. Patients with well-controlled HIV who are on HAART and have undetectable viral load are permitted to enroll;<br>• Use of probiotics. Probiotics must be discontinued a minimum of 2 weeks before CC administration and patients are not permitted to take probiotics during the course of immunotherapy treatment;<br>• Use of natural supplements including prebiotics. Prebiotics must be discontinued a minimum of 2 weeks before CC administration and patients are not permitted to take other prebiotics during the course of immunotherapy treatment;<br>• Use of antibiotics within 2 weeks of enrollment in the study; a. If a patient requires antibiotics during CC treatment, they are permitted to stay on the study.<br>• Expected to require any other form of systemic anti-neoplastic therapy while on study (radiation therapy is permitted);<br>• In the last year, has a known history of a malignancy requiring anti-neoplastic treatment. a. NOTE: This time requirement does not apply to patients who underwent successful definitive resection of basal or squamous cell carcinoma of the skin, superficial bladder cancer, in situ cancers including cervical cancer, breast cancer, melanoma, or other in situ cancers;<br>• Symptomatic central nervous system (CNS) metastases<br>• Leptomeningeal involvement (leptomeningeal enhancement on MRI/CT imaging and/or positive CSF cytology);<br>• Has an uncontrolled autoimmune disease that requires systemic steroids or immunosuppressive agents;a. Patients with vitiligo, type I diabetes, well controlled hypothyroidism due to Hashimoto disease, resolved childhood asthma/atopy are permitted to enroll.<br>• A history of (non-infectious) pneumonitis that required steroids or current pneumonitis.<br>• Has serious concomitant illnesses, such as: impaired cardiovascular function or clinically significant cardiovascular disease (uncontrolled congestive heart failure requiring treatment (NYHA grade > 3), uncontrolled hypertension, acute myocardial cardiac ischemia or unstable angina < 2 months prior to study entry, and severe cardiac arrhythmia), active inflammatory bowel disorders.<br>• Active kidney disease/severe chronic kidney or liver disease or hematological blood test alteration that would preclude safe administration of chemotherapy at the discretion of the sponsor.<br>• Has an active infection requiring systemic therapy;<br>• Patient has received a live vaccine within 4 weeks prior to the first dose of treatment a. Note: Seasonal influenza vaccines for injection are generally inactivated flu vaccines and are allowed; however intranasal influenza vaccines (e.g., Flu-Mist®) are live attenuated vaccines, and are not allowed. COVID-19 vaccinations are not live vaccinations and are allowed.<br>• Has known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial<br>• Known life-threatening or severe allergy to CC at the discretion of the sponsor |