Essai Clinique

Généré le 17 mai 2025 à partir de

Titre	Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial
Protocole ID	CAPTUR/PM.1
ClinicalTrials.gov ID	NCT03297606
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Type étude	Traitement
Médicament	Olaparib, Dasatinib, Nivolumab + Ipilimumab, Axitinib, Bosutinib, Crizotinib, Palbociclib, Sunitinib, Temsirolimus, Erlotinib, Trastuzumab + Pertuzumab, Vemurafenib + Cobimetinib, Vismodegib
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	Montréal
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Statut	Actif en recrutement
But étude	Cancer drugs which target the effects of abnormal gene changes are called 'targeted therapies'. This study, called PM.1 or CAPTUR, will include some targeted therapies that are currently available. The purpose of this study is to find out what are the effects on a patient and their cancer when they are given a targeted therapy drug that is specific to an abnormal gene change in their cancer.
Critères d'éligibilité	• Adult (≥ 18 yrs) patient with a histologically?proven incurable metastatic solid tumour (excluding primary brain tumours), multiple myeloma or B cell non? Hodgkin lymphoma (excluding CLL, SLL and HCL), for whom there is no standard treatment known to prolong life, or who has refused such treatment. • ECOG performance status 0-2. • Patients must have normal organ and bone marrow function measured within 4 weeks prior to administration of study treatment as follows: • Hemoglobin ≥ 100.0 g/L with no blood transfusions (packed red blood cells and platelet transfusions) in the past 28 days prior to start of study treatment; • Absolute neutrophil count: • 1.5 x 10^9/L • No features suggestive of MDS/AML on peripheral blood smear; • Platelets ≥ 100 x 10^9/L (or ≥ 50 x 10^9/L if bone marrow involvement by myeloma or lymphoma). • Total bilirubin ≤ 1.5 x UNL. • AST (SGOT)/ALT (SGPT) ≤ 2.5 x institutional upper limit of normal value unless liver metastases are present in which case they must be < 5 x ULN; • Serum creatinine alone is not sufficient for eligibility. Patients matched to olaparib must have creatinine clearance estimated of ≥ 51 mL/min using the Cockcroft?Gault equation or based on a 24 hour urine test. • Adequate hepatic function assessed by: • total serum bilirubin ≤ 2.0 the upper limit of normal (UNL), unless resulting from hemolysis, Gilbert's syndrome, or live infiltration with tumour • aspartate aminotransferase (AST)/alanine aminotransferase (ALT) ≤ 2.5 x the upper limit of normal (ULN) • Patients must have measurable disease • Results must be available from tumour genomic or protein expression testing (if used to identify

	genetic variants), from one of the initiatives / groups listed in Appendix VII. The test may have been performed on the primary tumour or a metastatic deposit (including bone marrow), or blood, in a diagnostic or research laboratory and must reveal a potentially actionable variant. • Patient consent (Main Study Consent for the screening step) must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to the screening step to document their willingness to participate • Patients must be accessible for treatment and follow-up. Patients registered on this trial must be treated and followed at the participating centre or a CCTG IND site. This implies there must be reasonable geographical limits (for example: 1 ½ hour's driving distance) placed on patients being considered for this trial. • Women/men of childbearing potential must have agreed to use a highly effective contraceptive method.
Critères d'exclusion	• Patients with ongoing toxicity ≥ CTCAE grade 2, other than peripheral neuropathy, related to prior anti-tumour treatment. Patients with ongoing peripheral neuropathy of ≥ CTCAE grade 3 will be excluded. • Patients concurrently receiving any other anti-cancer therapy (cytotoxic, biologic, radiation, or hormonal other than for replacement) except for medications that are prescribed for supportive care but may potentially have an anti-cancer effect (e.g. megestrol acetate, bisphosphonates) or ongoing castration-intent therapy for prostate cancer. These medications must have been started ≥ one month prior to enrollment on this study. Patients may be on warfarin, low molecular weight heparin or direct factor Xa inhibitors, unless such therapies are prohibited by drug-specific ineligibility criteria. • Patients with known active progressive brain metastases. Patients with previously treated brain metastases are eligible, provided that the patient has not experienced a seizure or had a clinically significant change in neurological status within one month prior to screening. All patients with previously treated brain metastases must be stable (clinically and radiologically) for at least one month after completion of treatment and either off steroid treatment or only taking physiological doses of steroids prior to the screening step. • Patients with clinically significant pre-existing cardiac conditions, including uncontrolled or symptomatic angina, uncontrolled atrial or ventricular arrhythmias, or symptomatic congestive heart failure. • Patients with known left ventricular ejection fraction (LVEF) < 40%. • Patients with stroke (including TIA) or acute myocardial infarction within three months prior to the screening step. • Patients with acute gastrointestinal bleeding within one month prior to the screening step. • Patients with any other clinically significant medical condition which, in the opinion of the treating physician, makes it undesirable for the patient to participate in the study or which could jeopardize compliance with study requirements including, but not limited to: ongoing or active infection, significant uncontrolled hypertension, or severe psychiatric illness/social situations. • Lactating and nursing women • Patients who do not meet drug-specific eligibility requirements for the drug selected by the treating physician.