Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	Neoadjuvant Platform Trial in Patients With Surgically Resectable Non-Small Cell Lung Cancer (NSCLC)
Protocole ID	IND.242
ClinicalTrials.gov ID	NCT05714891
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase II
Type étude	Clinique
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Jonathan Spicer
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Statut	Actif en recrutement
Date d'activation	08-08-2023
But étude	This study is being done to answer the following question: What are the effects of new treatments on non-small cell lung cancer before surgery? The purpose of the pre-study screening is to test for biomarkers. The testing will be done using a sample of your tumor tissue. Each substudy will be looking at what effects a new drug has on the patients and their lung cancer, as well as any side effects of the treatment. The purpose of each substudy is to see if the biomarkers that were identified at screening can be used to determine treatment outcomes, like how the cancer cells respond to treatment and whether the study drug will shrink the tumour before surgery and prevent it from returning after surgery.

Critères d'éligibilité	• Histologically confirmed diagnosis of primary NSCLC within 90 days of enrollment to a substudy, according to WHO Classification of Tumours
	• Patients must be classified as Stage IA2 to IIIA according to the AJCC 8th edition TNM classification with disease that is amenable to anatomical surgical resection. Patients with multistation N2 disease are not eligible unless otherwise specified in a specific substudy
	• Pre-surgical staging of patients with newly diagnosed lung cancer should include: CT thorax, abdomen and pelvis; PET scan imaging; Brain MRI or CT brain with IV contrast. Patients with mediastinal lymph nodes suspicious for metastases on PET imaging are required to undergo invasive staging by EBUS or mediastinoscopy to confirm or disprove pathological involvement of suspected nodes.
	• All patients must have evaluable disease as defined by RECIST 1.1 although measurable disease is recommended.
	• Patients that are eligible for one or more substudies must consent for release of tissue biopsies, surgical specimens and blood samples for conduct of tissue analyses. If there is insufficient tissue to conduct the proposed research studies without exhausting the diagnostic biopsies, please consult CCTG
	• Patients must be ≥ 18 years of age
	• No prior anticancer therapy for treatment of NSCLC. Patients with a history of NSCLC treated in the curative setting may be eligible but must be discussed with CCTG prior to enrollment
	• Patient must have an ECOG performance status of 0 or 1
	• Patients with synchronous primary tumours may be eligible if all of the following conditions are met:
	  • The synchronous tumour is located within the planned resection area
	  • The radiological appearance of the tumour is compatible with ground-glass opacity

	(GGO) • The synchronous tumour is not FDG-avid on PET imaging • The local multidisciplinary thoracic oncology tumour board has approved the surgical treatment plan • Surgery for participants enrolled on this protocol will be according to generally accepted standards of care. Operative approach (VATS, RATS vs open) will be determined by the surgeon. Accepted types of resection must aim to achieve an R0 resection, as defined by the IASLC, including the highest resected mediastinal being negative for carcinoma. • Unless otherwise specified in specific substudies, surgery must be performed between 2 to 4 weeks following the last dose of neoadjuvant therapy • Patients must have adequate organ and marrow function within 7 days prior to enrollment • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. • Patient is able and willing to complete the Patient Related Outcomes questionnaire • Patients must be accessible for treatment and follow-up. • Protocol treatment is to begin within 2 working days of patient enrollment • Women/men of childbearing potential must have agreed to use a highly effective contraceptive method
Critères d'exclusion	• Presence of locally advanced, unresectable cancer (regardless of stage), or metastatic cancer (Stage IV). • Patients with a history of other malignancy may be eligible if curatively treated and/or the malignancy does not affect the determination of safety or efficacy of the investigational regimen (must be confirmed with CCTG). • Clinically significant, uncontrolled cardiac disease and/or recent cardiac events (within 6 months), such as: • Unstable angina or myocardial infarction within 6 months prior to enrollment; • Symptomatic congestive heart failure (defined as New York Heart Association Grade II or greater);, • Documented cardiomyopathy;, • Clinical significant cardiac arrhythmias; • Uncontrolled hypertension defined by a Systolic Blood Pressure (SBP) ≥ 160 mm Hg and/or Diastolic Blood Pressure (DBP) ≥ 100 mm Hg, unless controlled prior to first dose of study treatment. • Patients with a significant cardiac history, even if controlled, should have LVEF ≥ 50% • History or current diagnosis of ECG abnormalities indicating significant risk of safety for participants participating in the study such as: • Concomitant clinically significant cardiac arrhythmias e.g. sustained ventricular tachycardia, and clinically significant second or third-degree AV block without a pacemaker; • History of familial long QT syndrome or known family history of Torsades de Pointes; • Resting QT interval corrected with Fridericia's formula (QTcF) > 480 msec on screening ECG or congenital long QT syndrome. • Patients with prior allogenic bone marrow transplant, double umbilical cord blood transplantation (dUCBT) or solid organ transplant. • Patients with active or uncontrolled infections or with serious illnesses or medical conditions which would not permit the patient to be managed according to the protocol. This includes but is not limited to: • Known clinical diagnosis of tuberculosis; • Pneumonitis or any history of pneumonitis requiring steroids (any dose); • Known primary immunodeficiency; • For Hepatitis B (HBV), Hepatitis C (HCV) and human immunodeficiency virus (HIV) infections, requirements will be substudy dependent. • History of hypersensitivity to any drugs in any substudy, or to drugs of similar chemical class. • Concurrent treatment with other investigational drugs or anti-cancer therapy. • Pregnant or breastfeeding women. • Patients who are unable to swallow oral medication and/or have impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of the specific substudy drug(s) • Patients with a history of non-compliance to medical regimens.