Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	Une étude randomisée de phase II pour évaluer l'efficacité et la sécurité d'un protocole d'escalade de dose de radiation adapté et métaboliquement sélectif pour les patients atteints d'un cancer du poumon non à petites cellules (NSLC) localement avancé qui reçoivent une chimioradiothérapie définitive.
Protocole ID	PET-BOOST
ClinicalTrials.gov ID	NCT02788461
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase II
Stade	Localement avancé
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	A randomized phase II trial to assess the efficacy and safety of selective metabolically adaptive radiation dose escalation in locally advanced non-small cell lung cancer receiving definitive chemoradiotherapy. Eligible and consenting patients will be randomized to receive conventional chemoradiotherapy or chemoradiotherapy with a radiation (RT) integrated boost. All patients will receive a fludeoxyglucose-positron emission tomography (FDG-PET) scan within two weeks prior to starting treatment. The primary outcome is to determine if dose escalation to metabolically active tumor subvolumes will reduce local-regional failure rate at 2 years.
Critères d'éligibilité	• Patients who are at least 18 years old and are able to consent • Patients who will undergo Chemo-RT as primarily modality of treatment • Patients with a primary tumor or node measuring at least 10mm on CT scan • Patients with a PET avid tumor having Standardized Uptake Values (SUV) > 4 • Patients with Eastern Cooperative Oncology Group (ECOG) status 0-2 within 4 weeks of randomization
Critères d'exclusion	• Trimodality patients who have surgery as part of curative treatment • Previous radiotherapy to intended treatment volumes • Active invasive malignancy other than lung cancer • Active pregnancy • Poor respiratory function (Forced Expiratory Volume < 1.0 or Diffusing Capacity < 50% age-adjusted normal) • ECOG status > 2 • Pre-treatment complete blood count/differential showing inadequate bone marrow reserve (absolute neutrophil count < 1800 cells/mm3 or platelets < 100 000 cells/mm3 or hemoglobin < 90g/L), measured within 4 weeks of registration • AST, ALT or total bilirubin > 2.5 times the upper limit of normal, measured within 4 weeks of registration • Unintentional weight loss >10% over 3 months within 4 weeks of registration • Severe active co-morbidity defined by: • Significant history of uncontrolled cardiac disease; i.e. uncontrolled hypertension, unstable

angina, myocardial infarction within the last 6 months, uncontrolled congestive heart failure, cardiomyopathy with decreased ejection fraction
- Transmural myocardial infection requiring intravenous antibiotics at the time of registration
- Chronic Obstructive Pulmonary Disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy within 30 days before randomization
- Acquired immune deficiency syndrome (AIDS) based on the current Centre for Disease Control definition; note, however, that HIV testing is not required for entry into this protocol