Radiotherapy to Block Oligoprogression In Metastatic Non-Small-Cell Lung Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Metastatic disease (stage IV) detected on imaging and histologically and/or cytologically confirmed NSCLC as per the WHO Classification of Tumors and AJCC 8th Edition TNM Classification, without an actionable driver mutation, for whom either ICI alone or combination ICI + chemotherapy is indicated * Oligoprogression on first-line ICI +/- chemotherapy systemic therapy after at least 3 cycles. * All sites of oligoprogression can be safely treated with SBRT or ablative radiotherapy as determined by radiation treatment preplan, including availability and tolerability of necessary technologies (e.g., active breathing control, MRLinac, fiducial insertion, etc.) and accounting for previous radiotherapy overlap. Safety must be assessed and determined by a radiation oncologist. * Patients with treated CNS disease who have radiologic and clinical evidence of stable brain metastases, with no evidence of cavitation or hemorrhage in the brain lesion, are eligible providing that they are asymptomatic and do not require corticosteroids (must have discontinued steroids at least 1 week prior to randomization). * Candidate for regulatory approved SOC second-line systemic therapy options if randomized to Arm 2. * Participants must be ≥ 18 years of age. * ECOG performance status of 0, 1 or 2. * Participants that received prior adjuvant/neoadjuvant/consolidation systemic therapy (including chemotherapy and ICI) are eligible if at least 6 months have elapsed between the completion of prior therapy and start of first-line treatment for metastatic disease. * Participants must have recovered to ≤ grade 1 from all reversible toxicity related to prior systemic therapy. * Previous surgery related to NSCLC in the curative or metastatic disease setting is permitted. Previous major surgery is permitted provided that surgery occurred at least 28 days prior to participant enrollment and that wound healing has occurred. * Prior external beam radiation related to NSCLC in the metastatic disease setting is permitted provided a minimum of 14 days (2 weeks) have elapsed between the last dose of radiation and date of enrollment. Patients that received prior external beam radiation therapy in the NSCLC curative disease setting (including the primary lesion) are eligible. Oligoprogressive lesions previously treated with external beam radiation are eligible as long they are clinically asymptomatic, and re-treatment is possible according to the investigator. * Prior conventional, non-stereotactic radiotherapy for palliative purposes is allowed, and if the palliated lesion subsequently progressed but asymptomatic not requiring immediate RT, the lesion can still be counted toward one of the five oligoprogressive lesions. * For Arm 1, SBRT must be initiated within 3 weeks of participant enrollment. * Participant is able (i.e. sufficiently fluent) and willing to complete the quality of life and/or health utility questionnaires in either English, French, or Spanish. * Reimbursement of continued SOC ICI and chemotherapy systemic therapies may not be uniform across all sites. In the event that site/investigator is unable to provide access to the drug, participant will not be eligible for this trial. * Participants must be accessible for treatment and follow-up. Investigators must assure themselves the participants enrolled on this trial will be available for complete documentation of the treatment, adverse events, and follow-up. * Participants of childbearing potential must have agreed to use a highly effective contraceptive method.

Exclusion Criteria:

* Large-cell neuroendocrine carcinoma (LCNEC), pulmonary carcinoid tumour or mixed small cell and non-small cell lung cancer are not eligible. * Presence of leptomeningeal disease. * Pregnancy. * Serious medical conditions in which radiotherapy of target lesions is contraindicated (e.g., scleroderma, Ataxia Telangiectasia (ATM), interstitial lung disease (ILD), Child-Pugh C liver function). * Any other condition in which in the judgement of the investigator would make the patient inappropriate for study entry. * Patients who are not on actively on ICI or ICI + chemotherapy. * Participants with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial. * Concomitant medications should only exclude participants from trial participation when clinically relevant known or predicted drug-drug interactions or potential overlapping toxicities will impact safety or efficacy; please consult the relevant product monographies. * Concurrent treatment with other anti-cancer therapy, including investigational agents. * Live attenuated vaccination administered within 30 days prior to enrollment/randomization.

Conditions & Interventions

Interventions:
RADIATION: SBRT, OTHER: Second-line standard of care therapy
Conditions:
Non-small Cell Lung Cancer

More Information

Contact(s): Pierre-Olivier Gaudreau - p-ogaudreau@ctg.queensu.ca
Principal Investigator:
IRB
Number:
System ID: NCT06686771
