

Reduced CT + Anti-PD-1 as First Line Tx in Vulnerable Older Adults w/Adv <50% PD-L1 Non-Small Cell Lung Cancer (NSCLC)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histologically or cytologically confirmed diagnosis of non-small cell lung cancer (NSCLC) (either squamous or non- squamous) * Stage IV disease OR have recurrent disease and not be candidates for curative treatment such as combined chemo-radiation * No previous line of treatment in the recurrent or metastatic setting. Neoadjuvant or adjuvant treatment more than 6 months before enrollment is acceptable. * Age 70 or meeting frailty definition or above at the date of signing informed consent * Absence of driver mutations that have first line Food and Drug Administration (FDA) approved targeted therapy * PD-L1 tumor proportion score (TPS) of less than 50% * Eastern Cooperative Oncology Group (ECOG) PS of 0-3 * Have measurable disease based on RECIST 1.1 as determined by the local site investigator/radiology assessment * Absolute neutrophil count (ANC) $\geq 1,000/\mu\text{L}$ * Platelets $\geq 75,000/\mu\text{L}$ * Hemoglobin (Hgb) ≥ 8.0 g/dL (transfusion permitted) * Total bilirubin $\leq 2 \times$ institutional upper limit of normal (ULN) * Aspartate amino transferase (AST)serum glutamic-oxaloacetic transaminase (SGOT) /alanine aminotransferase (ALT)serum glutamic-pyruvic transaminase (SGPT) $\leq 5.0 \times$ institutional ULN * Ability to understand and the willingness to sign a written informed consent document

Exclusion Criteria:

* Participants with life expectancy of less than 3 months at the time of enrollment * Has active autoimmune disease that has required systemic treatment in past 2 years (ie, with use of disease modifying agents, or immunosuppressive drugs) * Diagnosis of interstitial lung disease * Creatinine clearance of ≤ 30 mL/min * Symptomatic, untreated central nervous system (CNS) disease or leptomeningeal disease. Patients with asymptomatic or treated CNS disease are eligible * Required ongoing use of immunosuppressive medication, including steroids, with the following allowable exceptions: * Doses less than or equal to the equivalent of prednisone 10 mg daily * Short courses of steroids that are discontinued prior to enrollment * Inhaled, intranasal and/or topical steroids * Dexamethasone taper for treating vasogenic edema associated with CNS disease

Conditions & Interventions

Interventions:

DRUG: Reduced Dose of Chemotherapy and Immunotherapy

Conditions:

Non-small Cell Lung Cancer, NSCLC, Advanced Non-small Cell Lung Cancer, Metastatic Non Small Cell Lung Cancer

Keywords:

Non-Small Cell Lung Cancer, NSCLC

More Information

Contact(s): Massey IIT Research Operations - masseyepd@vcu.edu

Principal Investigator:

Phase: PHASE2

IRB

Number:

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