Background Lung cancer has higher incidence and mortality in the elderly population, although substantial evidence confirms the efficacy of PD-1/L1 inhibitors in combination with chemotherapy for advanced non-small cell lung cancer (NSCLC) regardless of PD-L1 expression. However, efficacy and safety of immunotherapy in elderly NSCLC remains unclear, with most evidence is sourced from subgroup analysis of prospective clinical trials. Elderly lung cancer patients often have more underlying diseases and function of major organs decreases with ageing, safety is certainly a key factor that must be carefully considered when these patients receive treatment because of poor tolerability. Therefore, we designed the study of tislelizumab in combination with pemetrexed and bevacizumab for the treatment of elderly non-squamous NSCLC. To improve safety and tolerability, we remove the more toxic platinum from the chemotherapy regimen, and the anti-angiogenic agent bevacizumab, with relatively mild adverse effect, was added to avoid decreased efficacy. This study aims to explore the efficacy and safety of this treatment regimen in elderly NSCLC patients.

Methods This open-label, single arm, phase I clinical study is enrolling patients aged ≥65 years with histologically or cytologically confirmed, untreated IIIB/IIIC/IV(according to AJCC 8th) non-squamous NSCLC. Patients must have measurable disease per RECIST v1.1; ECOG PS of 0 or 1; without harboring EGFR-sensitizing mutation or ALK and ROS1 gene translocation; no active autoimmune disease, bleeding risk, or coagulation disorders. Patients will receive 4 cycles of pemetrexed (500mg/m², d1) Q3W and tislelizumab (200mg, d4) Q3W in combination with bevacizumab (7.5mg/kg, d1) Q3W followed by tislelizumab (200mg, d1) Q3W and bevacizumab (7.5mg/kg, d1) Q3W, until disease progression, unacceptable AEs, investigator/patient decision or 2 years. The primary endpoint is objective response rate (ORR) by RECIST v1.1. Secondary endpoints include overall survival (OS), progress-free survival (PFS), duration of response (DOR), health-related quality of life (HRQoL) and safety. HRQoL is assessed using EORTC QLQ-C30 questionnaires; AEs are graded according to NCI CTCAE v5.0. This study will enroll 30 patients and enrollment is ongoing.

Trial Registration ClinicalTrials.gov NCT05273814

REFERENCES

Ethics Approval The study was approved by Tianjin Medical University Cancer Institute & Hospital Ethics Board, approval number E20210962A.