



P2.364: A Clinical Study of Tislelizumab With or Without Anti-Angiogenic Agents as Adjuvant Therapy After Neoadjuvant Treatment and Surgery in Patients With Phase II–III Non-Small Cell Lung Cancer

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INTRODUCTION

- Adjuvant immunotherapy has been approved in multiple countries to reduce the risk of cancer recurrence For patients with resectable stage II–III NSCLC.
- The advantages of ICIs in the adjuvant setting include maintaining surgical outcomes, potentially eliminating residual micro-metastatic disease that cannot be eradicated preoperatively, and reversing the immunosuppressive tumor microenvironment after surgery.
- Although neoadjuvant immunotherapy has already become a standard treatment option for resectable NSCLC, the proportion of patients achieving pCR after neoadjuvant therapy remains relatively low.
- The optimal adjuvant strategy for patients with pCR versus non pCR after surgery is still under debate.
- pCR reflects only local tumor regression and does not capture occult micro-metastasis elsewhere in the body. Moreover, suboptimal pathological assessment in clinical practice may lead to overestimation of pCR. Patients who did not achieve pCR had even poorer outcomes, highlighting an unmet need for individualized adjuvant treatment strategies.
- Anti angiogenic agents can block VEGF mediated immunosuppression, enhance T cell infiltration into tumors, and inhibit immunosuppressive cytokines and regulatory T cells in the tumor microenvironment, thereby augmenting the antitumor activity of PD 1 blockade.
- Therefore, this study administers adjuvant tislelizumab monotherapy to patients who achieve pCR, and tislelizumab combined with an anti angiogenic agent to those without pCR.
- This intensified postoperative strategy aims to reduce recurrence risk, eliminate micro-metastatic disease, improve cure rates, and ultimately achieve long term survival for patients with poor postoperative prognosis.

STATEMENT

Artificial intelligence (AI)-assisted tools (Microsoft Copilot) were used to support language translation and content organization. No scientific conclusions were generated by the AI tool. All content was independently reviewed by the presenter.

METHODS

This study is an open label, single center, prospective clinical trail planning to enroll 60 patients with stage II–IIIB NSCLC who have completed neoadjuvant therapy and achieved R0 resection. Based on postoperative pathological assessment, patients will be assigned to two treatment cohorts: pCR cohort: Patients who achieve pCR will receive adjuvant tislelizumab monotherapy (200 mg Q3W) for up to 1 year, starting 2–8 weeks after surgery. Non pCR cohort: Patients without pCR will receive tislelizumab (200 mg Q3W) combined with an anti angiogenic agent for up to 1 year, starting 4–8 weeks after surgery. The choice of anti angiogenic agent will depend on histological subtype: bevacizumab for non squamous NSCLC and anlotinib for squamous NSCLC. The primary endpoint of this study is DFS. The study protocol has been approved by the Ethics Committee of the General Hospital of Ningxia Medical University. Clinical trial identification: ChiCTR2600121659

Key inclusion criteria

- stage II–IIIB NSCLC who have completed neoadjuvant (AJCC 9th)
- ECOG PS 0-1
- Age ≥ 18 years and < 70 years

Stratification Factors

- Histology: Sq vs Non-Sq NSCLC
- Disease Stage: Stage II vs Stage III
- PD-L1 Expression: PD-L1 $< 1\%$ vs PD-L1 $\geq 1\%$

Pathological Assessment

pCR tislelizumab monotherapy (200 mg Q3W) for up to N=30 1 year

Non-pCR tislelizumab (200 mg Q3W) combined with anti N=30 angiogenic agent for up to 1 year

Anti-angiogenic Therapy: Bevacizumab for Nsq 7.5-15 mg/kg, IV on Day 1 of each cycle Q3W; Anlotinib for Sq :10 mg, PO, QD on Days 1-14 of each 21-day cycle Q3W

KEY INCLUSION CRITERIA

1. Age ≥ 18 and < 70 years.
2. No prior antitumor therapy, including radiotherapy, chemotherapy, targeted therapy, immunotherapy, or traditional Chinese medicine for cancer.
3. Histologically confirmed resected stage II–IIIB squamous or non-squamous NSCLC, AJCC 9th edition/UICC staging system.
4. ECOG PS 0–1.
5. Adequate organ function, meeting all of the following criteria:
 - (1) No blood transfusion or growth factor support within ≤ 14 days prior to screening blood tests.
 - (2) Coagulation function :International normalized ratio (INR) ≤ 2.3 or prothrombin time (PT) ≤ 6 seconds above the upper limit of normal (ULN) (Note: INR or PT $\leq 1.5 \times$ ULN; activated partial thromboplastin time (aPTT) $\leq 1.5 \times$ ULN.)
 - (3) Urine protein $< 2+$ by dipstick.
6. Voluntarily provides written informed consent.

KEY EXCLUSION CRITERIA

1. History of pneumonia, upper gastrointestinal bleeding, esophageal fistula, esophageal perforation, or thoracic abscess within 6 months prior to the start of study treatment.
2. Active autoimmune disease or a history of autoimmune disease with a risk of recurrence.
3. Any active malignancy within ≤ 2 years prior to enrollment
4. Prior anti-angiogenic therapy or radiotherapy for the current lung cancer.
5. Presence of EGFR or ALK sensitizing mutations.
6. Active hemoptysis requiring clinical intervention.
7. History or evidence of bleeding diathesis.
8. Uncontrolled hypertension despite optimal medical therapy
9. Clinically significant hemoptysis within 3 months prior to study entry, or active bleeding, or bleeding tendency
10. Active bleeding or coagulation abnormalities (INR > 2.0 , PT > 16 s), bleeding disorders, or current treatment with thrombolytic, anticoagulant, or antiplatelet agents.