

Neoadjuvant adebrelimab combined with chemotherapy followed by surgical resection for limited-stage small-cell lung cancer: a cohort study

Liwei Yang¹, Ping Wang², Zhifeng Li¹, Si Li²

1.Department of thoracic surgery, The Fourth Hospital of Hebei Medical University, Shijiazhuang, China
2.Department of Respiratory Medicine, The Fourth Hospital of Hebei Medical University, Shijiazhuang, China

BACKGROUND

- Small-cell lung cancer (SCLC) accounts for 10-15% of all lung cancers and is a highly malignant neuroendocrine tumor. Concurrent chemoradiotherapy is the current standard of care for limited-stage SCLC. However, the prognosis for patients with SCLC remains poor. Chemotherapy combined with immunotherapy has significantly improved survival in patients with extensive-stage SCLC.
- Neoadjuvant immunotherapy combined with chemotherapy followed by surgery has demonstrated encouraging efficacy, favorable tolerability, and substantial survival benefits in patients with resectable SCLC. However, clinical data remain limited, and the optimal number of neoadjuvant cycles has yet to be defined.
- Therefore, this prospective study aims to investigate the efficacy and safety of neoadjuvant adebrelimab combined with chemotherapy in patients with limited-stage SCLC and determine whether the number of neoadjuvant cycles administered prior to surgery influences treatment efficacy, with the goal of improving therapeutic strategies for this population.

PROCEDURE

Key Inclusion Criteria

- 18-75 years;
- Histologically or cytologically confirmed SCLC;
- Clinical stage: T1-4 N0-2M0;
- ECOG PS 0 or 1;
- No prior systemic anti-tumor therapy or chest radiotherapy;
- No contraindications to surgery.

Cohort 1 (N=20)

adebrelimab 1200mg, iv, d1, etoposide 100mg/m², iv, d 1-3, cisplatin 75mg/m² or carboplatin (AUC=5), iv, d1, 2 cycles

Cohort 2 (N=20)

adebrelimab 1200mg, iv, d1, etoposide 100mg/m², iv, d 1-3, cisplatin 75mg/m² or carboplatin (AUC=5), iv, d1, 3 cycles

4-6 weeks

Surgery

until disease progression, death or unacceptable toxicity.

METHODS

Study Design:

- This is a prospective, two-cohort, exploratory study.
- Enroll 40 patients with previously untreated limited-stage SCLC. Patients will be assigned to one of two cohorts based on the investigator's assessment of baseline clinical characteristics, including but not limited to disease stage and organ function.
- Cohort 1 (n = 20) will receive two cycles, and Cohort 2 (n = 20) will receive three cycles of neoadjuvant therapy.
- Following the completion of neoadjuvant therapy, patients will undergo surgical assessment within 4 to 6 weeks. Inoperable patients will receive chemoradiotherapy with or without immunotherapy. Postoperative treatment will be at the investigator's discretion.

Study Endpoints:

- Primary endpoint:** pathological complete response (pCR).
- Secondary endpoints:** major pathological response (MPR), R0 resection rate, objective response rate (ORR), event-free survival (EFS), overall survival (OS), and safety.