



# Thymosin $\alpha$ -1 plus chemo-immunotherapy followed by TRT as first-line treatment for ES-SCLC: a prospective, single-arm trial

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## BACKGROUND

Extensive-stage small-cell lung cancer (ES-SCLC) is a highly aggressive malignancy with poor prognosis. Immune checkpoint inhibitor (ICI) combined with chemotherapy has become the first-line standard treatment for ES-SCLC, but the median overall survival (OS) is only 12–13 months, leaving unmet clinical needs. Thoracic radiotherapy (TRT) sequential to chemoimmunotherapy exerts a synergistic anti-tumor effect by remodeling the tumor immune microenvironment, yet it is associated with increased risks of radiation pneumonitis and hematological toxicity.

## RATIONALE

1. Thymosin  $\alpha$ -1 (T $\alpha$ -1), a classic immune modulator, can promote T cell maturation and dendritic cell activation, reverse the immunosuppressive tumor microenvironment, and reduce radiation- and chemotherapy-related toxicities in non-small-cell lung cancer.
2. Based on these, we designed this study to explore the efficacy and safety of T $\alpha$ -1 combined with chemoimmunotherapy followed by TRT in the first-line treatment of ES-SCLC.

## STUDY DESIGN

This is a prospective, multicenter, single-arm clinical trial, which will be conducted from June 2025 to December 2027 across 5 clinical centers, with a planned enrollment of 30 treatment-naïve ES-SCLC patients. Eligible patients are aged 18–75 years with ECOG PS 0–1, adequate organ function, and no active autoimmune diseases or uncontrolled comorbidities. The treatment is divided into chemoimmunotherapy, TRT, and immune maintenance phase. The primary efficacy endpoints are PFS (from the first dose of T $\alpha$ -1 to disease progression or death) and OS (from the first dose of T $\alpha$ -1 to all-cause death). The secondary endpoints include ORR, DCR, the incidence of  $\geq$ grade 2 pneumonitis (from radiotherapy initiation to 2 months after completion), grade 3–4 lymphopenia and other SAEs. For statistical analysis, Kaplan-Meier method and log-rank test will be used to calculate PFS and OS; Clopper-Pearson method will be applied to estimate ORR and DCR with 95% confidence intervals (CI); descriptive statistics will be used for safety evaluation. All tests are two-sided, with  $P < 0.05$  considered statistically significant. Patient recruitment will be completed from October 2025 to December 2026, followed by treatment and follow-up until December 2027, and data management and final analysis from January to June 2028.

## OBJECTIVES

1. To preliminarily investigate the impact of T $\alpha$ -1 combined with ICI plus chemotherapy followed by TRT on the survival outcomes (progression-free survival [PFS], and overall survival [OS]) of patients with ES-SCLC.
2. To evaluate the effect of T $\alpha$ -1 on tumor control (objective response rate [ORR], disease control rate [DCR]) and the incidence of treatment-related toxicities ( $\geq$ grade 2 pneumonitis, grade 3–4 lymphopenia, other serious adverse events [SAEs]) in this combined regimen.

## REFERENCES & ACKNOWLEDGEMENTS

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### Key Inclusion Criteria:

1. Treatment-naïve ES-SCLC
2. ECOG PS 0/1
3. Expected survival > 3 months
4. Adequate organ function

N=30

### Treatment Schema

#### Phase I: Induction

- Chemo: Etoposide + Cisplatin/Carboplatin
- PD-1 inhibitor: Q3W
- T $\alpha$ -1: 1.6 mg SC, BIW

#### Phase II: Thoracic Radiotherapy

- Radiotherapy: 30Gy/10fx
- T $\alpha$ -1: 1.6mg, SC, Tiw

#### Phase III: Immune Maintenance

- PD-1 inhibitor: Q3W
- T $\alpha$ -1: 1.6mg, SC, BIW
- Continue until PD, death, or 2 years

### Study endpoint

- Primary : PFS
- Secondary :
  1.  $\geq$ g2 pneumonitis
  2. OS
  3. ORR
  4. DCR

Figure 1. Overview of study design