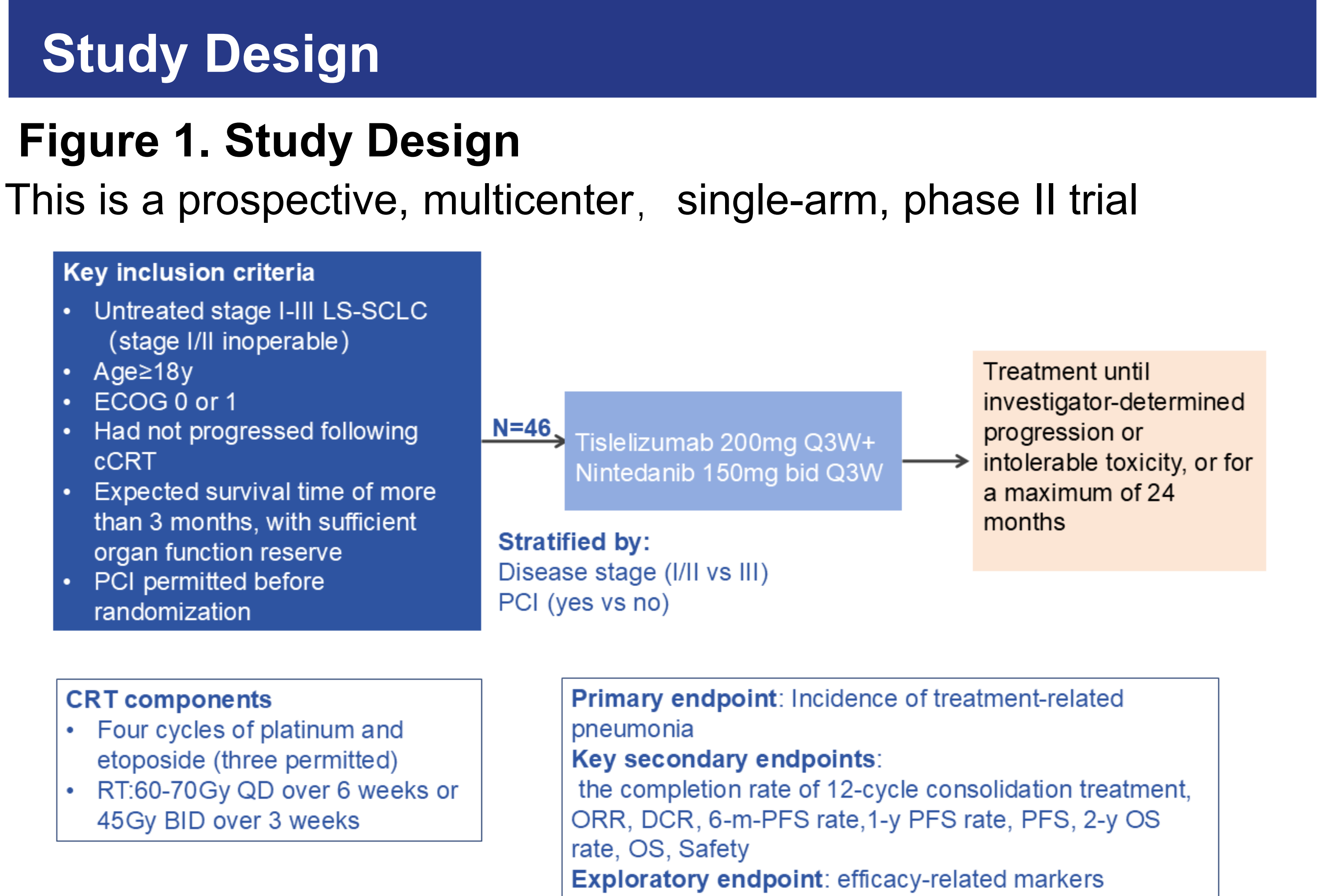


Background

- Limited-stage small cell lung cancer (LS-SCLC) is an aggressive neuroendocrine tumor marked by rapid proliferation and early dissemination. Despite initial responses to concurrent or sequential chemoradiotherapy (cCRT/sCRT), most patients progress, highlighting the need for effective consolidation strategies. The ADRIATIC trial demonstrated the potential of consolidation durvalumab, yet reported a 38.2% incidence of any-grade pneumonitis (3.1% grade 3–4), which was the leading cause of the 21% treatment discontinuation rate due to adverse events. Thus, mitigating the overlapping risk of radiation- and immune-related pneumonitis in the post-CRT consolidation setting remains a critical unmet clinical need.
- Nintedanib, a multi-target tyrosine kinase inhibitor targeting VEGFR, FGFR, and PDGFR, is approved for idiopathic pulmonary fibrosis. Beyond its antifibrotic indication, accumulating evidence supports anti-inflammatory and antifibrotic effects of nintedanib in immune checkpoint inhibitor–related and radiation-induced pneumonitis. In oncology, nintedanib exerts triple anti-angiogenic activity by blocking these receptor pathways, thereby suppressing endothelial cell proliferation, pericyte recruitment, and vascular remodeling, ultimately depriving tumors of blood supply and nutrients.
- The combination of immune checkpoint inhibitors and anti-angiogenic agents exerts synergistic effects in LS-SCLC through tumor microenvironment modulation. Accordingly, tislelizumab (anti–PD-1) plus nintedanib constitutes a rational therapeutic pairing. This study evaluates the efficacy, safety, and exploratory biomarkers of this regimen as consolidation therapy in LS-SCLC patients without disease progression after definitive cCRT or sCRT.
- This prospective trial will establish the biological rationale and clinical feasibility of tislelizumab plus nintedanib as a novel consolidation strategy for LS-SCLC, informing the design of subsequent larger randomized controlled trials.

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- Key Inclusion Criteria**
- Age ≥18 years old, gender is not limited;
 - Patients with limited-stage small cell lung cancer confirmed by histology or cytology and who have not progressed after standard concurrent chemoradiotherapy;
 - ECOG PS 0–1
 - The expected survival period is ≥3 months
 - Prophylactic craniocerebral radiotherapy is permitted before consolidation treatment
- Key Exclusion Criteria**
- Patients with previous or concurrent malignant tumors in other systems
 - Previously received other systemic treatments for the current lung cancer in addition to induction chemoradiotherapy, including chemotherapy, immunotherapy, targeted therapy or anti-angiogenic therapy, etc.
 - Patients with unsatisfactory blood pressure control after drug treatment (systolic blood pressure ≥160mmHg, diastolic blood pressure ≥100mmHg);
 - There are obvious factors that affect the absorption of oral drugs, such as inability to swallow, chronic diarrhea and intestinal obstruction, etc.

- Clinically significant hemoptysis (more than 50 ml per day) within 3 months before the study, or clinically significant bleeding symptoms or obvious bleeding tendency
- During the treatment process, researchers determined that the possibility of the patient's tumor invading important blood vessels and causing fatal bleeding was relatively high.

Methods

- This prospective, single-arm, multicenter, exploratory study will enroll 46 patients with histologically or cytologically confirmed LS-SCLC who have completed definitive chemoradiotherapy and achieved disease control (complete response, partial response, or stable disease). Eligible patients will receive consolidation therapy with tislelizumab (200 mg IV, Q3W, Day 1) plus nintedanib (150 mg orally, twice daily). Treatment will continue until disease progression per RECIST v1.1, unacceptable toxicity, death, withdrawal of consent, or completion of 24 months of therapy.
- The primary endpoint is the incidence of treatment-related pneumonitis, defined as the proportion of patients developing any-grade radiation pneumonitis or immune-related pneumonitis from the first study drug administration to 90 days after the last dose.
- Secondary endpoints include the 12-cycle consolidation therapy completion rate, objective response rate (ORR), disease control rate (DCR), progression-free survival (PFS) and its 6-month and 1-year rates, overall survival (OS) and its 2-year rate, and safety.
- Exploratory analyses will evaluate potential prognostic and predictive biomarkers.

Current status

- Enrollment began in June 2026
- Clinical trial information: NCT07485920