A Prospective, Open-Label, Single-Arm Phase II Study of Tislelizumab Combined With TAC Regimen as Neoadjuvant Therapy for TNBC

Reserach Unity: Army Medical Center of Army Medical University

Department： Breast and Thyroid Surgery

Major Reseracher： Yan Xu

Participating Centers： Chongqing General Hospital, People’s Hospital of Dali Bai Autonomous Prefecture

Version 1.3 Version Date:10 October 2025

Principal Investigator Statement

I have carefully read and fully understood this study protocol (Version: 1.3; Version Date: October 10, 2025). I agree to all contents specified in the protocol and confirm that the study will be conducted in strict accordance with the approved protocol.

I acknowledge that the study shall not be initiated without prior approval from the clinical research management department and the ethics committee. I understand that this study will be performed in compliance with the ethical principles of the Declaration of Helsinki, relevant laws and regulations for clinical research, and institutional policies. I will be responsible for all clinical and medical decisions related to this study. I guarantee timely and appropriate medical treatment for study participants who experience any adverse events during the study period, and will record and report all adverse events in accordance with relevant regulatory requirements.

I promise to record all study data truthfully, accurately, completely, and in a timely manner. I commit to maintaining the confidentiality of all personal information and relevant data of study participants throughout the research process.

Principal Investigator Name: Yan Xu

Principal Investigator Signature: 

Protocol Summary

Protocol Title	A Prospective, Open-Label, Single-Arm Phase II Study of Tislelizumab Combined With TAC Regimen as Neoadjuvant Therapy for TNBC
Primary Study Objective	To observe and evaluate the efficacy and safety of tislelizumab combined with TAC regimen as neoadjuvant therapy for triple-negative breast cancer (TNBC), and to preliminarily explore the molecular mechanism of tislelizumab plus TAC in patients with triple- negative breast cancer.
Study Type	Multicenter, prospective, single-arm, phase II clinical trial
Study Design	☐ Randomized controlled trial ☐ Non-randomized controlled study ☑ Single-arm study
	☐ Single center ☑ Multicenter
	Blinding：☐ Yes ☑ No
Study Subjects	Patients with clinical stage I–III triple-negative breast cancer who are scheduled to receive radical mastectomy following neoadjuvant therapy
Interventions	Neoadjuvant therapy with tislelizumab combined with TAC regimen for TNBC Treatment regimen: Albumin-bound paclitaxel injection, 260 mg/m^2 , IV, D1, Q3W, for 6 cycles Anthracyclines (including epirubicin, pirarubicin, doxorubicin, etc.) at standard doses, Q3W, for 6 cycles Cyclophosphamide, 500 mg/m^2 , Q3W, for 6 cycles Tislelizumab injection, 200 mg, IV, D1, Q3W, for 6 cycles

Outcome measures	Primary Outcome measures: Pathological complete response rate (pCR, ypT0/Tis ypN0) Secondary Outcome measures: Event-free survival (EFS), overall survival (OS); Incidence of treatment-related adverse events (TRAE) and safety profile; Results of whole-exome sequencing (WES) and transcriptome sequencing.
Sample	36
Statistical Analysis	Professional statisticians will conduct the statistical analysis and take part in all stages including trial design, conduct, analysis and summary. After the protocol and case report forms are finalized, the statistical analysis plan (SAP) will be established and revised appropriately during the study. A statistical analysis report will be provided upon completion of data analysis. SPSS 16.0 (SPSS Inc., USA) will be used for data analysis. Between-group comparisons for parametric variables will use the t - test; chi-square test or Fisher ’ s exact test for categorical variables. Cumulative survival time and survival rates will be estimated by the Kaplan – Meier method. Univariate and multivariate survival analyses will be performed with Cox proportional hazards models, and the Log-rank test for survival comparison. Statistical significance is defined as two-sided $p < 0.05$.
Study Period	May 2024-December 2026